

Cc: Carroll, Bart <BCarroll@isdh.IN.gov>

Subject: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

Good morning:

Bart and I would like to set up a phone call to discuss the ISDH's Non-Party Requests for Production. Are you available tomorrow afternoon for a call? It looks like both of our afternoons are open, so whatever time works for you all, we can be available.

ADRIENNE BRUNE

Attorney

Agency Ethics Officer

Office of Legal Affairs

Indiana State Department of Health

317.233.7270 office

317.233.7143 fax

abrune@isdh.in.gov

www.StateHealth.in.gov



Indiana
A State that Works

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Brune, Adrienne

From: John Bucy <john@johnbucy.com>
Sent: Tuesday, January 30, 2018 5:50 PM
To: Clare Deitchman; Brune, Adrienne
Cc: ISDH Court Administrator
Subject: Re: Assignment Acknowledgement ACL-000132-18

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Judge Deitchman,

The time works for us also.

Thank you,

John

Bucy & Associates, PLLC
6633 Hwy. 290 East, Suite 104
Austin, Texas 78723
Telephone: (512) 291-6505
Facsimile: (512) 291-6558
Email: john@johnbucy.com

From: Clare Deitchman <cdeitchmanlaw@att.net>
Reply-To: Clare Deitchman <cdeitchmanlaw@att.net>
Date: Monday, January 29, 2018 at 7:55 AM
To: Adrienne Brune <abrune@isdh.in.gov>, "john@johnbucy.com" <john@johnbucy.com>
Cc: ISDH Court Administrator <courtadministrator@isdh.in.gov>
Subject: Fw: Assignment Acknowledgement ACL-000132-18

Counsel,

I have been assigned as the Administrative Law Judge (ALJ) to hear the appeal of the license denial for Whole Woman's Health Alliance. I would like to set this for a pre-hearing conference call for purposes of scheduling. Would the two of you be available for a brief conference call on Monday, February 12, 2018 at say at 9:30 EST which would be 8:30 (CST) (Austin Texas Time).

If so, I will send out a Notice in today's mail. If that does not work for you, please provide alternative dates during that week.

Clare Deitchman

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----- Forwarded Message -----

From: "Miller, Rochelle" <RocMiller@isdh.IN.gov>

To: Clare Deitchman <cdeitchmanlaw@att.net>

Cc: "Brune, Adrienne" <ABrune@isdh.IN.gov>; "Carroll, Bart" <BCarroll@isdh.IN.gov>; ISDH Court Administrator <CourtAdministrator@isdh.IN.gov>; "Snyder, Randall" <RSnyder1@isdh.IN.gov>; "Whitson, Terry" <TWhitson@isdh.IN.gov>; "Gilliland, Karen" <Karen.Gilliland@fssa.IN.gov>

Sent: Friday, January 26, 2018 3:51 PM

Subject: Assignment Acknowledgement ACL-000132-18

Good afternoon Judge Deitchman,

Please see the attached assignment acknowledgement regarding Whole Woman's Health Alliance's license application denial. Hard copy with attachment to follow via mail.

Thank you,

ROCHELLE MILLER

Court Administrator

Office of Legal Affairs

Indiana State Department of Health

317.233.7540 office

317.234.6278 fax

rocmler@isdh.in.gov

www.StateHealth.in.gov

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Brune, Adrienne

From: Brune, Adrienne
Sent: Monday, January 29, 2018 9:24 AM
To: 'Clare Deitchman'; john@johnbucy.com; Carroll, Bart
Cc: ISDH Court Administrator
Subject: RE: Assignment Acknowledgement ACL-000132-18

Judge Deitchman:

February 12, 2018 at 9:30 a.m. EST works for Bart and me.

Thanks,

Adrienne

ADRIENNE BRUNE
Attorney
Agency Ethics Officer

Office of Legal Affairs
Indiana State Department of Health
317.233.7270 office
317.233.7143 fax
abrune@isdh.in.gov
www.StateHealth.in.gov



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From: Clare Deitchman [mailto:cdeitchmanlaw@att.net]
Sent: Monday, January 29, 2018 8:55 AM
To: Brune, Adrienne <ABrune@isdh.IN.gov>; john@johnbucy.com
Cc: ISDH Court Administrator <CourtAdministrator@isdh.IN.gov>
Subject: Fw: Assignment Acknowledgement ACL-000132-18

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Counsel,

I have been assigned as the Administrative Law Judge (ALJ) to hear the appeal of the license denial for Whole Woman's Health Alliance. I would like to set this for a pre-hearing conference call for purposes of scheduling. Would the two of you be available for a brief conference call on Monday, February 12, 2018 at say at 9:30 EST which would be 8:30 (CST) (Austin Texas Time).

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Clare Deitchman

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----- Forwarded Message -----

From: "Miller, Rochelle" <RocMiller@isdh.IN.gov>

To: Clare Deitchman <cdeitchmanlaw@att.net>

Cc: "Brune, Adrienne" <ABrune@isdh.IN.gov>; "Carroll, Bart" <BCarroll@isdh.IN.gov>; ISDH Court Administrator <CourtAdministrator@isdh.IN.gov>; "Snyder, Randall" <RSnyder1@isdh.IN.gov>; "Whitson, Terry" <TWhitson@isdh.IN.gov>; "Gilliland, Karen" <Karen.Gilliland@fssa.IN.gov>

Sent: Friday, January 26, 2018 3:51 PM

Subject: Assignment Acknowledgement ACL-000132-18

Good afternoon Judge Deitchman,

Please see the attached assignment acknowledgement regarding Whole Woman's Health Alliance's license application denial. Hard copy with attachment to follow via mail.

Thank you,

ROCHELLE MILLER

Court Administrator

Office of Legal Affairs

Indiana State Department of Health

317.233.7540 office

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Brune, Adrienne

From: Dipti Singh <dsingh@lawyeringproject.org>
Sent: Monday, April 30, 2018 8:21 PM
To: Brune, Adrienne; Carroll, Bart
Cc: Kathrine D. Jack, Jack Law Office LLC; Stephanie Toti
Subject: RE: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

**** This is an EXTERNAL email. Exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email. ****

Dear Adrienne and Bart,

Please see our responses below in red.

- The ISDH's understanding as to where the current discovery stands is as follows: With regard to the Party Requests for Production, WWHA is agreeable to the proposed modifications from the ISDH's April 20, 2018 email (attached) for Request #s 1, 2, 3, and 4. WWHA indicated it does not have documents to produce for Request # 5 except to the extent it possesses documents related to joint litigation and advocacy efforts (i.e., signage and promotional material for mutual advocacy endeavors). I believe we requested WWHA update its response accordingly. The ISDH also asked WWHA update its response to Interrogatory # 8.
- Response: You have correctly characterized our agreement with respect to Requests #1-4. With respect to Request #5, we explained our position that the Request was overly broad. There are no reasonable means, including no reasonable search terms, to search for documents in response to such a broad request. We provided, as an example, the Texas litigation in which WWHA is a co-plaintiff with nonparty entities. Producing all documents related to that case would be neither relevant nor likely to lead to the discovery of admissible evidence and unduly burdensome. Bart agreed that ISDH would not want those documents. Similarly, if a third-party e-mailed WWHA and one or more of the nonparty entities about an event or wholly unrelated issue, that email would be responsive to Request #5 even though it would shed no light on the relationship between WWHA and the nonparty entities. WWHA has agreed to produce documents responsive to requests for information regarding the absence of a relationship between WWHA and the nonparty entities.
- With regard to the Non-Party Requests, it is our understanding the Non-Parties agreed to produce the documents as listed in #1 and #2 of the ISDH's April 18, 2018 email (attached). The Non-Parties indicated they would not produce documents in response to the email's third request (surveys, findings, notices, complaints, citations, warnings, and other documents alleging a violation of the rules, regulations, or laws under which any clinic which performs abortions, of any kind, and which is operated by one or more of the Non Parties that has been issued for the three-year period immediately preceding the application date (August 11, 2017)). The ISDH is looking into retaining outside counsel to aide it in our Non-Party Requests, as well as other means of retrieving the documents (e.g., public records requests to the various state agencies). We're trying to determine which would better serve the ISDH.
- Response: This correctly characterizes our conversation. Please note that we explained that there are no documents responsive to Request No. 1(d).

Sincerely,
Dipti

From: Brune, Adrienne <ABrune@isdh.IN.gov>
Sent: Monday, April 30, 2018 6:05 AM
To: Dipti Singh <dsingh@lawyeringproject.org>; Carroll, Bart <BCarroll@isdh.IN.gov>

Cc: Stephanie Toti <stoti@lawyeringproject.org>; Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>
Subject: RE: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

Good morning:

The ISDH's understanding as to where the current discovery stands is as follows: With regard to the Party Requests for Production, WWHHA is agreeable to the proposed modifications from the ISHD's April 20, 2018 email (attached) for Request #s 1, 2, 3, and 4. WWHHA indicated it does not have documents to produce for Request # 5 except to the extent it possesses documents related to joint litigation and advocacy efforts (i.e., signage and promotional material for mutual advocacy endeavors). I believe we requested WWHHA update its response accordingly. The ISDH also asked WWHHA update its response to Interrogatory # 8.

With regard to the Non-Party Requests, it is our understanding the Non-Parties agreed to produce the documents as listed in #1 and #2 of the ISDH's April 18, 2018 email (attached). The Non-Parties indicated they would not produce documents in response to the email's third request (surveys, findings, notices, complaints, citations, warnings, and other documents alleging a violation of the rules, regulations, or laws under which any clinic which performs abortions, of any kind, and which is operated by one or more of the Non Parties that has been issued for the three-year period immediately preceding the application date (August 11, 2017)). The ISDH is looking into retaining outside counsel to aide it in our Non-Party Requests, as well as other means of retrieving the documents (e.g., public records requests to the various state agencies). We're trying to determine which would better serve the ISDH.

Please let me know if you disagree on any of that.

Regards,

Adrienne

From: Dipti Singh [<mailto:dsingh@lawyeringproject.org>]

Sent: Friday, April 27, 2018 9:49 PM

To: Brune, Adrienne <ABrune@isdh.IN.gov>; Carroll, Bart <BCarroll@isdh.IN.gov>

Cc: Stephanie Toti <stoti@lawyeringproject.org>; Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>

Subject: RE: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

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Dear Bart and Adrienne,

We had one remaining item to get back to you about: the Department's request for "Operating Agreements." Subject to previously made responses and objections, each of the nonparty entities we represent will produce documents in response to this request.

Thanks very much.

Sincerely,
Dipti

From: Dipti Singh

Sent: Wednesday, April 18, 2018 10:02 AM

To: Brune, Adrienne <ABrune@isdh.IN.gov>; Stephanie Toti <stoti@lawyeringproject.org>; Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>

Cc: Carroll, Bart <BCarroll@isdh.IN.gov>

Subject: RE: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

Thank you for the modified requests—we will review.

Tomorrow at 3:30 et works for us. We can use the below call-in information.

Phone: (605) 472-5528

Pin: 268831

Best,
Dipti

From: Brune, Adrienne <ABrune@isdh.IN.gov>

Sent: Wednesday, April 18, 2018 8:37 AM

To: Dipti Singh <dsingh@lawyeringproject.org>; Stephanie Toti <stoti@lawyeringproject.org>; Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>

Cc: Carroll, Bart <BCarroll@isdh.IN.gov>

Subject: RE: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

Good morning:

Sorry for the delay. Bart and I have been unable to meet and discuss a summary until just now. We're happy to meet tomorrow. Would a time between 1:30 and 3:30 work?

For each request to the Non Parties, we would like complete production of the requested items. In an effort to expeditiously resolve this without having to take the lengthy step of utilizing outside counsel, the ISDH is amenable to making some concessions. The ISDH is agreeable to modifying the requests as follows:

1. To satisfy the ISDH's requests of (1)(a), (1)(b), (1)(c), (1)(e), and (1)(g), we propose the Non Parties provide the Operating Agreements, Articles of Incorporation, and Member Lists (if any) for the Non Parties in effect from August 11, 2017 to January 3, 2018. The ISDH does not object to the Non Parties redacting information regarding how members are paid or other financial terms.
2. (1)(d): Any and all meeting minutes of the Non Parties' Boards of Directors regarding or mentioning Whole Woman's Health Alliance for the three-year period immediately preceding the application date (August 11, 2017). If there is not a Board of Directors for each entity, then any and all meeting minutes of its managers regarding or mentioning Whole Woman's Health Alliance for the three-year period immediately preceding the application date (August 11, 2017). This includes Whole Woman's Health Alliance under its current and former names during this time period.
3. (1)(h): All surveys, findings, notices, complaints, citations, warnings, and other documents alleging a violation of the rules, regulations, or laws under which any clinic which performs abortions, of any kind, and which is operated by one or more of the Non Parties that has been issued for the three-year period immediately preceding the application date (August 11, 2017).

Thank you for your consideration of the above modifications to the Non Party requests.

Adrienne

From: Dipti Singh [mailto:dsingh@lawyeringproject.org]

Sent: Wednesday, April 18, 2018 9:47 AM

To: Brune, Adrienne <ABrune@isdh.IN.gov>; Stephanie Toti <stoti@lawyeringproject.org>; Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>

Cc: Carroll, Bart <BCarroll@isdh.IN.gov>

Subject: Re: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

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Good morning, Bart and Adrienne.

I am writing to postpone our call until tomorrow. We haven't yet received the summary of what you'd like to discuss with respect to the nonparty requests and a phone call would be most productive after we have had an opportunity to review and consider your outstanding discovery issues. Could you email us the summary today and speak with us tomorrow afternoon ET instead?

Thanks very much.

Sincerely,

Dipti Singh*

Senior Counsel & Strategy Director

Lawyering Project

811 W. 7th St., 12th floor

Los Angeles, CA 90017

Phone: (646) 480-8973

Fax: (646) 480-8828

dsingh@lawyeringproject.org

*Admitted to practice in California

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From: Dipti Singh

Sent: Tuesday, April 17, 2018 10:10:26 AM

To: Brune, Adrienne; Stephanie Toti; Kathrine D. Jack, Jack Law Office LLC

Cc: Carroll, Bart

Subject: RE: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

Good afternoon.

We are available at 12 pm et tomorrow. As we discussed yesterday, if you could send us a summary of the issues you'd like to discuss in advance of the call, we would appreciate it. We can use the below call-in information for the call:

Phone: (605) 472-5528

Pin: 268831

Thanks very much.

Sincerely,
Dipti

From: Brune, Adrienne <ABrune@isdh.IN.gov>
Sent: Tuesday, April 17, 2018 7:45 AM
To: Stephanie Toti <stoti@lawyeringproject.org>; Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>; Dipti Singh <dsingh@lawyeringproject.org>
Cc: Carroll, Bart <BCarroll@isdh.IN.gov>
Subject: Whole Woman's Health Alliance (ACL-000132-18) Non-Party Requests for Production Phone Call Request

Good morning:

Bart and I would like to set up a phone call to discuss the ISDH's Non-Party Requests for Production. Are you available tomorrow afternoon for a call? It looks like both of our afternoons are open, so whatever time works for you all, we can be available.

ADRIENNE BRUNE

*Attorney
Agency Ethics Officer*

*Office of Legal Affairs
Indiana State Department of Health
317.233.7270 office
317.233.7143 fax
abrune@isdh.in.gov
www.StateHealth.in.gov*



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Brune, Adrienne

From: Carroll, Bart
Sent: Friday, April 13, 2018 5:07 PM
To: Dipti Singh; Brune, Adrienne; Stephanie Toti; john@johnbucy.com; Kathrine D. Jack, Jack Law Office LLC
Subject: RE: ACL-000132-18

Thank you so much. That time (3:45 est) will work great. We would appreciate you circulating a call in number for the call.

Sincerely,

BART CARROLL, JD
Litigation Chief

*Office of Legal Affairs
Indiana State Department of Health
317.233.7766 office
317.234.6278 fax
bcarroll@isdh.in.gov
www.StateHealth.in.gov*



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From: Dipti Singh [mailto:dsingh@lawyeringproject.org]
Sent: Friday, April 13, 2018 2:54 PM
To: Brune, Adrienne <ABrune@isdh.IN.gov>; Carroll, Bart <BCarroll@isdh.IN.gov>; Stephanie Toti <stoti@lawyeringproject.org>; john@johnbucy.com; Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>
Subject: Re: ACL-000132-18

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Adrienne,

Good afternoon. We are available at 3:45 et on Monday. Please let us know if you have a call in number you'd like to use. If not, I can circulate one.

Thanks very much.

Best,

Dipti

Dipti Singh*

Senior Counsel & Strategy Director

Lawyering Project

811 W. 7th St., 12th floor

Los Angeles, CA 90017

Phone: (646) 480-8973

Fax: (646) 480-8828

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From: Brune, Adrienne <ABrune@isdh.IN.gov>

Sent: Friday, April 13, 2018 6:48:35 AM

To: Dipti Singh; Carroll, Bart; Stephanie Toti; john@johnbucy.com; Kathrine D. Jack, Jack Law Office LLC

Subject: ACL-000132-18

Good morning:

Bart and I were hoping we could schedule a phone call on Monday to discuss discovery responses. I realize we're dealing with different time zones, so we can be flexible. Do you have availability Monday afternoon for a call?

Thanks,

Adrienne

ADRIENNE BRUNE

Attorney

Agency Ethics Officer

Office of Legal Affairs

Indiana State Department of Health

317.233.7270 office

317.233.7143 fax

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Brune, Adrienne

From: Dipti Singh <dsingh@lawyeringproject.org>
Sent: Thursday, April 05, 2018 10:24 PM
To: Carroll, Bart; Brune, Adrienne
Cc: Stephanie Toti; Kathrine D. Jack, Jack Law Office LLC
Subject: Whole Woman's Health Alliance v. Indiana State Department of Health, Cause No. ACL-000132-18 - Email 1 of 2
Attachments: Petitioner's Responses and Objections to Respondent's First Set of Requests for Production.pdf

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Dear Bart and Adrienne,

Please see attached Petitioner's Responses and Objections to Respondent's First Set of Requests for Production in the above-captioned matter. Documents Bates numbered WWHA000001-WWHA001521 will follow in a second e-mail. Please note that the attached contain material designated as confidential and/or trade secrets.

Sincerely,

Dipti Singh*

(Pronouns: she, her)

Senior Counsel & Strategy Director

Lawyering Project

811 W. 7th St., 12th floor

Los Angeles, CA 90017

Phone: (646) 480-8973

Fax: (646) 480-8828

dsingh@lawyeringproject.org

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STATE OF INDIANA)	BEFORE THE INDIANA STATE
) SS:	DEPARTMENT OF HEALTH
COUNTY OF MARION)	
)	CAUSE NO. ACL-000132-18

WHOLE WOMAN'S HEALTH)
ALLIANCE,)
)
<i>Petitioner,</i>)
v.)
)
INDIANA STATE DEPARTMENT)
OF HEALTH)
)
<i>Respondent.</i>)
)
)

**PETITIONER'S RESPONSES AND OBJECTIONS TO RESPONDENT'S FIRST SET
OF REQUESTS FOR PRODUCTION**

Pursuant to Rules 26 and 34 of the Indiana Rules of Trial Procedure, Petitioner Whole Woman's Health Alliance ("Petitioner"), by and through its undersigned counsel, hereby objects and responds to Respondent Indiana State Department of Health's ("Respondent's") First Request for Production, served on Petitioner on February 26, 2018 (the "Requests").

These responses are true and correct, so far as Petitioner is aware, according to information available at the time. Petitioner reserves the right to object to future discovery on the same or related matters and does not waive any objections by providing the documents referenced in these responses. Petitioner further reserves the right to object to the admissibility of any of its responses or any of the documents produced in response to Respondent's Requests, in whole or in part, at the hearing in this action, on any grounds, including, but not limited to, materiality, relevance, and privilege. Furthermore, a statement that documents will be produced

in response to a particular request does not mean that Petitioner knows such documents exist or are in its possession; it means only that if such documents exist, are in Petitioner's possession, are subject to discovery in this action, and can be located in a reasonable search of the most likely repositories of responsive documents, they will be produced.

OBJECTIONS TO INSTRUCTIONS

1. Petitioner specifically objects to Instruction Number 1 as naming nonparties to the case, including Petitioner's attorneys, thereby purporting to seek (i) documents not within the Petitioner's possession, custody, or control, and (ii) documents subject to the attorney-client and work product privileges. The Petitioner objects to producing, and will not produce, documents not within its possession, custody, or control, in response to any Request. The Petitioner further objects to producing, and will not produce in response to any Request, any confidential documents prepared by its attorneys for or in anticipation of litigation, any privileged communications between itself and its attorneys, or any communications among the Petitioner's attorneys, except to the extent discovery is permitted by the Indiana Rules of Trial Procedure. To the extent that any privileged information is inadvertently provided in these responses or any documents produced, such provision shall not constitute waiver of the privilege or immunity as to any such information and Respondent shall promptly return or destroy copies of any such information upon request.

OBJECTIONS TO DEFINITIONS

1. Petitioner specifically objects to the Definitions to the extent they purport to impose a burden or obligation beyond those required or permitted by the Indiana Rules of Trial Procedure or other applicable law.

GENERAL OBJECTIONS

Each of the following individual Request responses is made subject to and incorporates the following general objections.

1. Petitioner objects to the Requests to the extent that they seek to impose a burden or obligation beyond those required or permitted by the Indiana Rules of Trial Procedure, other applicable law, or any orders of the Administrative Law Judge.
2. Petitioner objects to the Requests to the extent they seek information already available to Respondent.
3. Petitioner objects to each of the Requests to the extent that they call for the production of documents that contain confidential or proprietary business information.
4. Petitioner objects to each of the Requests to the extent that they call for the production of documents that are protected by any privilege or immunity.

OBJECTIONS AND RESPONSES TO RESPONDENT'S FIRST SET OF REQUESTS FOR PRODUCTION TO PETITIONER

Subject to the foregoing objections, which are incorporated into each response whether or not repeated for emphasis, the Petitioner responds to each Request as follows:

REQUEST NO. 1: Copies of all records, notes, correspondence, emails, written communication, minutes, reviews, memorandum, voice mail recordings, other audio recordings, and other documents and electronic records with any information concerning potential conflicts of interest of any member of the Board of Directors.

RESPONSE NO. 1:

Petitioner objects to this Request to the extent it purports to require production of "all" documents and things without limitation (including as to subject matter, materiality, or

accessibility), as overly broad and unduly burdensome. Petitioner also objects to the vagueness and ambiguity of the undefined term “potential conflicts,” as it fails to make apparent the subject matter of this Request. Petitioner objects that the Request is not stated with reasonable particularity in that it fails to identify the categories or types of information sought. As a result, it is unclear what type or types of information Respondent seeks. Petitioner objects that the Request for “potential conflicts,” which calls for the production of documents that contain confidential or proprietary business information with no limitation or other specificity as to scope, is overly broad, unduly burdensome, oppressive, neither relevant to the subject matter of the pending action nor reasonably calculated to lead to the discovery of admissible evidence regarding any party’s claim or defense, and appears to be designed to harass or otherwise cause undue, unnecessary, immaterial, and irrelevant expenditure of Petitioner’s time and resources. Petitioner’s decision to exercise its legal right to seek review of Respondent’s denial of Petitioner’s application for a license to operate an abortion clinic does not entitle Respondent to use discovery as a fishing expedition into Petitioner’s business records.

Based on the foregoing objections, Petitioner has not produced any documents in response to this Request. Without waiving any of the foregoing objections, Petitioner is prepared to meet and confer with Respondent to ascertain whether agreement could be reached on production of documents that are properly discoverable.

REQUEST NO. 2: Copies of every document and record of any kind identified in the Indiana State Department of Health’s *First Set of Interrogatories* to Whole Woman’s Health Alliance, Interrogatory No. 8.

RESPONSE NO. 2:

Petitioner objects to the vagueness and ambiguity of this Request, as it fails to make apparent the scope of information sought. Subject to the forgoing objections, Petitioner hereby produces documents responsive to this Request that are Bates numbered WWHA000001-000041.

REQUEST NO. 3: A copy of each and every operating agreement, member agreement, or any other agreement between members concerning the LLC of Whole Woman's Health Alliance which the organization operated under at any time for the period from January 1, 2016 through December 31, 2017.

RESPONSE NO. 3:

Petitioner objects to the vagueness and ambiguity of this Request with respect to the term "members." Petitioner also objects that this Request is unintelligible with respect to the phrase "concerning the LLC of Whole Woman's Health Alliance which the organization operated under." Furthermore, Petitioner is a nonprofit entity and does not have "members" or an "operating agreement." To the extent this Request seeks organizational documents concerning Whole Woman's Health, LLC, Whole Woman's Health, LLC is a separate legal entity and any organizational documents of Whole Woman's Health, LLC are in its possession, custody, or control. It is unclear what documents Respondent seeks in response to this Request.

Based on the foregoing objections, Petitioner has not produced any documents in response to this Request. Without waiving any of the forgoing objections, Petitioner is prepared to meet and confer with Respondent to ascertain whether agreement could be reached on production of documents that are properly discoverable.

REQUEST NO. 4: All meeting minutes of the Board of Directors for the period from January 1, 2016 through December 31, 2017.

RESPONSE NO. 4:

Petitioner objects that the Request is not stated with reasonable particularity in that it fails to identify the categories or types of information sought within Petitioner's Board of Director meeting minutes. Petitioner objects that the Request for "all [Board of Director] meeting minutes," without limitation (including as to subject matter or materiality) or other specificity as to scope, is overly broad, unduly burdensome, oppressive, neither relevant to the subject matter of the pending action nor reasonably calculated to lead to the discovery of admissible evidence regarding any party's claim or defense, and appears to be designed to harass or otherwise cause undue, unnecessary, immaterial, and irrelevant expenditure of Petitioner's time and resources. Petitioner's decision to exercise its legal right to seek review of Respondent's denial of Petitioner's license to operate an abortion clinic does not entitle Respondent to use discovery as a fishing expedition into Petitioner's business records. Petitioner further objects to this request because it calls for the production of confidential and proprietary business information, and Respondent has informed us that it will disclose this information to members of the public upon request. Petitioner objects to the vagueness and ambiguity of this Request to the extent it fails to make apparent the scope of the information sought. Petitioner objects to this Request to the extent that it seeks documents protected from disclosure by the attorney-client privilege, work product doctrine, or any other applicable privilege or immunity.

Based on the foregoing objections, Petitioner has not produced any documents in response to this Request. Without waiving any of the foregoing objections, Petitioner is prepared

to meet and confer with Respondent to ascertain whether agreement could be reached on production of documents that are properly discoverable.

REQUEST NO. 5: All memoranda, interoffice communications, records, notes, correspondence, emails, written communication, minutes, reviews, memorandum, voice mail recordings, other audio recordings, and other documents and electronic records of Whole Woman's Health Alliance which refers to and/or otherwise mentions any of the following LLC organizations: Whole Woman's Health of McAllen, LLC; Whole Woman's Health of San Antonio, LLC; Whole Woman's Health of Fort Worth, LLC; Whole Woman's Health of the Twin Cities, LLC; Whole Woman's Health of Peoria, LLC; Whole Woman's Health of Beaumont, LLC; and Whole Woman's Health of Baltimore, LLC.

RESPONSES NO. 5:

Petitioner objects to this Request to the extent it purports to require production of "all" memoranda, interoffice communications, records, notes, correspondence, emails, written communication, minutes, reviews, memorandum, voice mail recordings, other audio recordings, and unspecified classes of "other documents," without limitation (including as to subject matter, materiality, or accessibility), as vague, overbroad, and unduly burdensome. Petitioner objects that the Request does not describe the documents and things sought with reasonable particularity to enable Petitioner to make a reasonable search. Petitioner further objects to this Request to the extent it seeks documents and things that "refer to and/or otherwise mention" the enumerated entities without limitation (including as to subject matter, materiality, or accessibility), as vague, overbroad, unduly burdensome, disproportional to the needs of the case, and because it purports to require production of documents and things without any limitation as to the subject matter of the above-captioned administrative appeal. Petitioner further objects to this Request because it

calls for the production of confidential and proprietary business information, and Respondent has informed us that it will disclose this information to members of the public upon request.

Petitioner also objects to this Request to the extent that it seeks documents protected from disclosure by the attorney-client privilege, work product doctrine, or any other applicable privilege or immunity.

Based on the foregoing objections, Petitioner has not produced any documents in response to this Request. Without waiving any of the foregoing objections, Petitioner is prepared to meet and confer with Respondent to ascertain whether agreement could be reached on production of documents that are properly discoverable.

REQUEST NO. 6: Provide copies of any and all documents and records not otherwise provided in these discovery requests and which the Facility or its representatives allege would tend to show that Whole Woman's Health of Baltimore is not an affiliate of Whole Woman's Health Alliance.

RESPONSE NO. 6:

Petitioner objects to this Request to the extent it purports to require production of "any and all" documents, without limitation (including as to subject matter, materiality, or accessibility) as overbroad and unduly burdensome. Petitioner objects to the Request as vague, ambiguous, unintelligible, and unduly burdensome to the extent it requires documents and records to indicate or establish a negative. Petitioner objects to the vagueness and ambiguity of the phrase "tends to show." Petitioner objects to the vagueness and ambiguity of the phrase "the Facility," which is not defined. Petitioner further objects to this Request to the extent it seeks documents and records not in Petitioner's possession, custody, or control.

Subject to the foregoing objections, Petitioner hereby produces non-privileged documents responsive to this Request that are Bates numbered WWHA000042-WWHA000058.

REQUEST NO. 7: Provide copies of any and all documents and records not otherwise provided in these discovery requests and which the Facility or its representatives allege would tend to show that Whole Woman's Health of Peoria is not an affiliate of Whole Woman's Health Alliance.

RESPONSE NO. 7:

Petitioner objects to this Request to the extent it purports to require production of "any and all" documents, without limitation (including as to subject matter, materiality, or accessibility) as overbroad and unduly burdensome. Petitioner objects to the Request as vague, ambiguous, unintelligible, and unduly burdensome to the extent it requires documents and records to indicate or establish a negative. Petitioner objects to the vagueness and ambiguity of the phrase "tends to show." Petitioner objects to the vagueness and ambiguity of the phrase "the Facility," which is not defined. Petitioner further objects to this Request to the extent it seeks documents and records not in Petitioner's possession, custody, or control.

Subject to the foregoing objections, Petitioner states that following a reasonable search, it has not identified any documents or records responsive to this Request that Petitioner has not already provided in Response No. 6.

REQUEST NO. 8: Provide copies of any and all documents and records not otherwise provided in these discovery requests and which the Facility or its representatives allege would tend to show that Whole Woman's Health of Twin Cities is not an affiliate of Whole Woman's Health Alliance.

RESPONSE NO. 8:

Petitioner objects to this Request to the extent it purports to require production of “any and all” documents, without limitation (including as to subject matter, materiality, or accessibility) as overbroad and unduly burdensome. Petitioner objects to the Request as vague, ambiguous, unintelligible, and unduly burdensome to the extent it requires documents and records to indicate or establish a negative. Petitioner objects to the vagueness and ambiguity of the phrase “tends to show.” Petitioner further objects to this Request to the extent it seeks documents and records not in Petitioner’s possession, custody, or control.

Subject to the foregoing objections, Petitioner states that following a reasonable search, it has not identified any documents or records responsive to this Request that Petitioner has not already provided in Response No. 6.

REQUEST NO. 9: Provide copies of any and all documents and records not otherwise provided in these discovery requests and which the Facility or its representatives allege would tend to show that Whole Woman’s Health of Fort Worth is not an affiliate of Whole Woman’s Health Alliance.

RESPONSE NO. 9:

Petitioner objects to this Request to the extent it purports to require production of “any and all” documents, without limitation (including as to subject matter, materiality, or accessibility) as overbroad and unduly burdensome. Petitioner objects to the Request as vague, ambiguous, unintelligible, and unduly burdensome to the extent it requires documents and records to indicate or establish a negative. Petitioner objects to the vagueness and ambiguity of the phrase “tends to show.” Petitioner objects to the vagueness and ambiguity of the phrase “the

Facility," which is not defined. Petitioner further objects to this Request to the extent it seeks documents and records not in Petitioner's possession, custody, or control.

Subject to the foregoing objections, Petitioner states that following a reasonable search, it has not identified any documents or records responsive to this Request that Petitioner has not already provided in Response No. 6.

REQUEST NO. 10: Provide copies of any and all documents and records not otherwise provided in these discovery requests and which the Facility or its representatives allege would tend to show that Whole Woman's Health of McAllen is not an affiliate of Whole Woman's Health Alliance.

RESPONSE NO. 10:

Petitioner objects to this Request to the extent it purports to require production of "any and all" documents, without limitation (including as to subject matter, materiality, or accessibility) as overbroad and unduly burdensome. Petitioner objects to the Request as vague, ambiguous, unintelligible, and unduly burdensome to the extent it requires documents and records to indicate or establish a negative. Petitioner objects to the vagueness and ambiguity of the phrase "tends to show." Petitioner objects to the vagueness and ambiguity of the phrase "the Facility," which is not defined. Petitioner further objects to this Request to the extent it seeks documents and records not in Petitioner's possession, custody, or control.

Subject to the foregoing objections, Petitioner states that following a reasonable search, it has not identified any documents or records responsive to this Request that Petitioner has not already provided in Response No. 6.

REQUEST NO. 11: Provide copies of any and all documents and records not otherwise provided in these discovery requests and which the Facility or its representatives allege would

tend to show that Whole Woman's Health of San Antonio is not an affiliate of Whole Woman's Health Alliance.

RESPONSE NO. 11:

Petitioner objects to this Request to the extent it purports to require production of "any and all" documents, without limitation (including as to subject matter, materiality, or accessibility) as overbroad and unduly burdensome. Petitioner objects to the Request as vague, ambiguous, unintelligible, and unduly burdensome to the extent it requires documents and records to indicate or establish a negative. Petitioner objects to the vagueness and ambiguity of the phrase "tends to show." Petitioner objects to the vagueness and ambiguity of the phrase "the Facility," which is not defined. Petitioner further objects to this Request to the extent it seeks documents and records not in Petitioner's possession, custody, or control.

Subject to the foregoing objections, Petitioner states that following a reasonable search, it has not identified any documents or records responsive to this Request that Petitioner has not already provided in Response No. 6.

REQUEST NO. 12: All documents referred to in responding to the Department's First Set of Interrogatories.

RESPONSE NO. 12:

Petitioner objects to this Request as overly broad, unduly burdensome, vague, ambiguous, and not reasonably specific insofar as it requests documents "referred to" in responding to the Respondent's interrogatories. Petitioner objects to this Request to the extent it seeks documents protected by attorney-client privilege or the attorney work product doctrine. Petitioner further objects to the Request to the extent it seeks confidential and proprietary information.

Petitioner states that all non-privileged documents that are responsive to this Request have been produced in response to prior requests.

REQUEST NO. 13: Any remaining documents that are relevant to the issues presented in the above-captioned administrative hearing.

RESPONSE NO. 13:

Petitioner objects to this Request to the extent it seeks documents protected from disclosure by any applicable privilege or immunity. Petitioner objects to this Request to the extent it seeks all remaining relevant documents, as Petitioner can only provide those documents of which it is aware. Petitioner objects to this Request because it is premature, as discovery in this matter is ongoing and Respondent has not yet responded to Petitioner's discovery requests. Petitioner also objects to this Request to the extent it seeks documents outside the possession, custody, or control of Petitioner.

Subject to the foregoing objections. Petitioner hereby produces non-privileged documents responsive to this Request that are Bates numbered WWHA000059_WWIIA001521.

REQUEST NO. 14: Produce the resume or curriculum vitae of each person you plan to call as an expert witness in this matter.

RESPONSE NO. 14:

Petitioner objects to this Request as premature and expressly reserves the right to supplement, clarify, revise, or correct this response. Subject to the foregoing objections. Petitioner states that at the present time there are no documents responsive to this Request.

Respectfully Submitted,

Dipti Singh
Dipti Singh, Att'y No. 6344-95-TA
Lawyering Project
811 W. 7th Street, 12th floor
Los Angeles, CA 90017
(646) 480-8973
dsingh@lawyeringproject.org

Stephanie Toti, Att'y No. 6343-95-TA
Lawyering Project
25 Broadway, 9th floor
New York, NY 10004
(646) 490-1083
stoti@lawyeringproject.org

Kathrine D. Jack (By Dipti Singh)
Kathrine D. Jack, Att'y No. 26851-49
JACK LAW OFFICE LLC
One Courthouse Plaza
P.O. Box 813
Greenfield, IN 46140
(317) 477-2300
kjack@jacklawoffice.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing has been served on counsel of record for Respondent, listed below, by e-mail, on April 5, 2018.

Bart Carroll
Adrienne Brune
Office of Legal Affairs
Indiana State Department of Health
2 North Meridian
Indianapolis, IN 42604
(317) 233-7766
BCarroll@isdh.IN.gov
ABrune@isdh.IN.gov

/s/Dipti Singh
Lawyering Project
811 W. 7th Street, 12th floor
Los Angeles, CA 90017
(646) 480-8973
dsingh@lawyeringprojcct.org

Brune, Adrienne

From: Brune, Adrienne
Sent: Friday, April 06, 2018 10:46 AM
To: 'Clare Deitchman'
Cc: ISDH Court Administrator
Subject: RE: Whole Woman's Health Alliance

Yeah, I believe we scheduled it during the first PHC.

From: Clare Deitchman [mailto:cdeitchmanlaw@att.net]
Sent: Friday, April 06, 2018 10:45 AM
To: Brune, Adrienne <ABrune@isdh.IN.gov>
Cc: ISDH Court Administrator <CourtAdministrator@isdh.IN.gov>
Subject: Re: Whole Woman's Health Alliance

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Okay, thanks. I wonder if we just did it during the prior call. I will get notices drafted and out today. I will be bringing the ISDH mail over early afternoon.
Clare

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From: "Brune, Adrienne" <ABrune@isdh.IN.gov>
To: Clare Deitchman <cdeitchmanlaw@att.net>
Cc: ISDH Court Administrator <CourtAdministrator@isdh.IN.gov>
Sent: Friday, April 6, 2018 10:40 AM
Subject: RE: Whole Woman's Health Alliance

Good morning:

I have it on my calendar for 4/17 at 9:30 a.m. I don't have a Notice of a 2nd PHC in my file, I don't recall getting one either.

Adrienne

From: Clare Deitchman [mailto:cdeitchmanlaw@att.net]
Sent: Friday, April 06, 2018 10:37 AM
To: Brune, Adrienne <ABrune@isdh.IN.gov>
Cc: ISDH Court Administrator <CourtAdministrator@isdh.IN.gov>
Subject: Re: Whole Woman's Health Alliance

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Adrienne,

Sorry I hit enter before I was done typing my question.

I have the above matter on my calendar for April 17, 2018 but no time. I don't see that I have sent it for a second prehearing conference call, and not sure what we are doing other than waiting for the temporary admissions to be granted.

Do you have this on your calendar? If not, I am going to have to send out some thing to get this moving along.

Clare

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From: Clare Deitchman <cdeitchmanlaw@att.net>
To: Adrienne Brune <abrune@isdh.in.gov>
Cc: ISDH Court Administrator <courtadministrator@isdh.in.gov>
Sent: Friday, April 6, 2018 10:34 AM
Subject: Whole Woman's Health Alliance

ACL-000132-18

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Brune, Adrienne

From: Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>
Sent: Monday, April 09, 2018 12:14 PM
To: Brune, Adrienne; Dipti Singh; Carroll, Bart
Cc: Stephanie Toti
Subject: RE: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

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Hello Adrienne,

We are willing to allow an extension until Wednesday to respond the Interrogatories, but won't agree to any further extensions.

Thank you!
Kathrine Jack

Jack Law Office LLC
One Courthouse Plaza
Greenfield Chamber of Commerce Building
Post Office Box 813
Greenfield, IN 46140

Office: 317-477-2300
Fax: 317-515-6377
kjack@jacklawoffice.com
www.jacklawoffice.com

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----- Original Message -----

Subject: RE: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18
From: "Brune, Adrienne" <ABrune@isdh.IN.gov>
Date: Mon, April 09, 2018 9:21 am
To: Dipti Singh <dsingh@lawyeringproject.org>, "Carroll, Bart" <BCarroll@isdh.IN.gov>
Cc: "Kathrine D. Jack, Jack Law Office LLC" <kjack@jacklawoffice.com>, Stephanie Toti <stoti@lawyeringproject.org>

Good morning, Dipti:

I apologize for the confusion. I was greeted this morning with several bounced back emails due to size. I am resending in the next five (5) emails. Please let me know if you do not receive the following five (5) emails not including this email.

Additionally, my client has asked that I request additional time for him to review the Interrogatories. We would like until Wednesday at the latest. Please let me know if that is an issue. I, again, apologize for the delay.

Thank you,

Adrienne

From: Dipti Singh [<mailto:dsingh@lawyeringproject.org>]

Sent: Friday, April 06, 2018 8:58 PM

To: Brune, Adrienne <ABrune@isdh.IN.gov>; Carroll, Bart <BCarroll@isdh.IN.gov>

Cc: Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>; Stephanie Toti <stoti@lawyeringproject.org>

Subject: RE: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

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Dear Adrienne,

I did not receive the 4:33 PM email included in the chain below. Could you resend it, please?

Also, we are in receipt of two documents that were sent as attachments: (1) Respondent's Response to the Requests and (2) a document entitled "RFP #13." Could you confirm that those are the only two documents you emailed us today? If we are missing any documents that you emailed today, could you please resend?

Thanks very much.

Sincerely,
Dipti

From: Brune, Adrienne <ABrune@isdh.IN.gov>

Sent: Friday, April 6, 2018 1:40 PM

To: Dipti Singh <dsingh@lawyeringproject.org>; Carroll, Bart <BCarroll@isdh.IN.gov>

Cc: Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>; Stephanie Toti <stoti@lawyeringproject.org>

Subject: RE: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

And lastly, attached is Respondent's Response to the Requests. Please let me know if you have any difficulty opening these.

Adrienne

From: Brune, Adrienne

Sent: Friday, April 06, 2018 4:33 PM

To: 'Dipti Singh' <dsingh@lawyeringproject.org>; Carroll, Bart <BCarroll@isdh.IN.gov>

Cc: 'Kathrine D. Jack, Jack Law Office LLC' <kjack@jacklawoffice.com>; 'Stephanie Toti' <stoti@lawyeringproject.org>

Subject: RE: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

Good afternoon:

This is email 1 of 2 containing Respondent's Responses to Petitioner's First Request for Production of Documents.

Thanks!

Adrienne

From: Brune, Adrienne

Sent: Friday, April 06, 2018 3:15 PM

To: 'Dipti Singh' <dsingh@lawyeringproject.org>; Carroll, Bart <BCarroll@isdh.IN.gov>

Cc: Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>; Stephanie Toti <stoti@lawyeringproject.org>

Subject: RE: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

Thanks, Dipti. Have a great weekend!

Adrienne

From: Dipti Singh [<mailto:dsingh@lawyeringproject.org>]

Sent: Friday, April 06, 2018 2:42 PM

To: Brune, Adrienne <ABrune@isdh.IN.gov>; Carroll, Bart <BCarroll@isdh.IN.gov>

Cc: Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>; Stephanie Toti <stoti@lawyeringproject.org>

Subject: Re: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

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Good afternoon, Adrienne. Understood.

Sincerely,
Dipti

Dipti Singh*
Senior Counsel & Strategy Director
Lawyering Project
811 W. 7th St., 12th floor
Los Angeles, CA 90017
Phone: (646) 480-8973
Fax: (646) 480-8828
dsingh@lawyeringproject.org
*Admitted to practice in California

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From: Brune, Adrienne <ABrune@isdh.IN.gov>
Sent: Friday, April 6, 2018 11:29:23 AM
To: Carroll, Bart; Dipti Singh
Cc: Kathrine D. Jack, Jack Law Office LLC; Stephanie Toti
Subject: RE: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

Good afternoon:

I'm finalizing the ISDH's Responses to the First Request for Production and will have those to you shortly. Our Interrogatories are awaiting signature with our Chief of Staff, who will need to verify and sign before we can send. He's locked in back-to-back meetings right now, and won't be able to get to review and sign by COB today. We will get the Interrogatory responses to you as soon as it's signed on Monday.

Thanks,

Adrienne

From: Carroll, Bart
Sent: Monday, April 02, 2018 10:30 AM

To: Dipti Singh <dsingh@lawyeringproject.org>; Brune, Adrienne <ABrune@isdh.IN.gov>

Cc: Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>; Stephanie Toti <stoti@lawyeringproject.org>

Subject: RE: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

Understood. Also, as discussed by telephone, we will have ISDH's responses out on Friday, April 6th.

BART CARROLL, JD
Litigation Chief

*Office of Legal Affairs
Indiana State Department of Health
317.233.7766 office
317.234.6278 fax
bcarroll@isdh.in.gov
www.StateHealth.in.gov*



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From: Dipti Singh [<mailto:dsingh@lawyeringproject.org>]

Sent: Friday, March 30, 2018 3:16 PM

To: Brune, Adrienne <ABrune@isdh.IN.gov>; Carroll, Bart <BCarroll@isdh.IN.gov>

Cc: Kathrine D. Jack, Jack Law Office LLC <kjack@jacklawoffice.com>; Stephanie Toti <stoti@lawyeringproject.org>

Subject: Re: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

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Dear Bart and Adrienne,

I am following up to request additional time, until Thursday, April 5, to respond to Respondent's First Request for Production.

Sincerely,

Dipti Singh*

Senior Counsel & Strategy Director
Lawyering Project
811 W. 7th St., 12th floor
Los Angeles, CA 90017
Phone: (646) 480-8973
Fax: (646) 480-8828
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*Admitted to practice in California

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From: Dipti Singh
Sent: Wednesday, March 28, 2018 7:43:44 PM
To: Brune, Adrienne; Carroll, Bart
Cc: Kathrine D. Jack, Jack Law Office LLC; Stephanie Toti
Subject: Whole Woman's Health Alliance v. Indiana State Department of Health, Case No. ACL-000132-18

Dear Bart and Adrienne,

Attached please find Petitioner's Responses and Objections to Respondent's First Set of Interrogatories in the above-captioned matter.

As we discussed by phone this afternoon, we will be in touch with respect to Petitioner's response to Respondent's First Request for Production by Monday, April 2, at the latest. Thank you.

Sincerely,

Dipti Singh*
(Pronouns: she, her)
Senior Counsel & Strategy Director
Lawyering Project
811 W. 7th St., 12th floor
Los Angeles, CA 90017
Phone: (646) 480-8973
Fax: (646) 480-8828
dsingh@lawyeringproject.org
*Licensed in California

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1

Brune, Adrienne

From: Brune, Adrienne
Sent: Wednesday, March 28, 2018 1:07 PM
To: 'etstecker@earthlink.net'
Subject: Whole Woman's Health Alliance
Attachments: WWHH SB App Denial Ltr 01.03.18.pdf

Dr. Stecker:

Attached is the *Notice of License Application Denial* issued January 3, 2018.

Thank you,

ADRIENNE BRUNE

Attorney

Agency Ethics Officer

Office of Legal Affairs

Indiana State Department of Health

317.233.7270 office

317.233.7143 fax

abrune@isdh.in.gov

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Brune, Adrienne

From: Snyder, Randall
Sent: Wednesday, January 03, 2018 11:21 AM
To: Brune, Adrienne
Subject: FW: Notice of the Legal Obligation of the Indiana State Department of Health ("ISDH") to Deny the Abortion Clinic Application of Whole Women's Health Alliance ("WWHA")
Attachments: Ltr.to.ISDH.AG.&.Holcomb.re.legally.deficient.WWHA.app.for.clinic_01-01-18.pdf; Pages from Ltr.to.ISDH.AG.&.Holcomb.EXHIBITS.1.through.6.for.Legal.Opinion_01-01-18-3.pdf

RANDY SNYDER, PT, MBA
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From: Shawn Sullivan [mailto:sullyatlaw@sbcglobal.net]
Sent: Wednesday, January 03, 2018 11:10 AM
To: Box, Kristina M <KBox@isdh.IN.gov>; Snyder, Randall <RSnyder1@isdh.IN.gov>
Cc: Shawn Sullivan <sullyatlaw@sbcglobal.net>
Subject: Notice of the Legal Obligation of the Indiana State Department of Health ("ISDH") to Deny the Abortion Clinic Application of Whole Women's Health Alliance ("WWHA")

**** This is an EXTERNAL email. Exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email. ****

Kristina Box, MD <KBox@isdh.in.gov>
Randall Snyder <rsnyder1@isdh.in.gov>

Please find attached a legal letter concerning the above referenced matter. Given the holiday, I just now received approval for the letter from the last of my growing list of represented parties in this matter.

And please be aware that the parties I represent are resolved to fight this matter until the goal is accomplished -- defending against the placement of a new violation-prone abortion clinic in South Bend.

I believe its contents are self-explanatory, but I still encourage you to call me to discuss the matter.

Note that Exhibits 7 through 16, due to their size, will arrive in a separate email, to immediately follow this one.

A hard copy will be provided to you via Federal Express or hand delivery. If you desire to receive it by fax, please provide your facsimile number.

Sincerely,

/s/ Shawn Sullivan

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January 1, 2018
Solemnity of the Mother of God

URGENT via Priority Mail, Email, and Facsimile

The Honorable Kristina Box
via kbox@isdh.in.gov and
Indiana State Department of Health
State Health Commissioner
2 North Meridian Street, 4A
Indianapolis, IN 46204

Randall Snyder
via rsnyder1@isdh.in.gov and
Indiana State Department of Health
Director of Acute Care Division
2 North Meridian Street
Indianapolis, IN 46204

Re: *Notice of the Legal Obligation of the Indiana State Department of Health ("ISDH") to Deny the Abortion Clinic Application of Whole Women's Health Alliance ("WWHA")*

Dear Dr. Kristina Box:

I write in opposition to the application of WWHA (a Texas Corporation), to operate an abortion clinic in South Bend, and I write on behalf of a number of similarly situated Indiana groups and citizens, including The Life Center of South Bend, TLC Advocates, 40-Days-for-Life, South Bend, Inc., Hoosiers for Life, Indiana Liberty Coalition, Madalyn's Hope, the Apostolate of Divine Mercy in Service of Life, Marriage and the Family, and the abortion-mothers who were denied their informed consent due to the ISDH's failure to properly regulate the Women's Pavilion in South Bend.

Be advised that in addition to the notice supplied in this letter, the parties represented herein are again launching the "Answer the C.A.L.L. (Citizens Against Licensing the Lawless)" campaign to urge the ISDH to consider all of the evidence concerning WWHA's reputation and history of violations when applying Indiana's laws related to the licensing of abortion clinics. The need for another "Answer the C.A.L.L." campaign is highlighted by ISDH's recent failure to properly regulate the Women's Pavilion in South Bend, enabling that clinic to illegally operate for years while leaving a trail of victimized mothers and families (as evidenced below). The undersigned will be representing any additional groups or persons that are interested in signing-on to the campaign to enforce their rights against the inaction and transgressions of ISDH.

I. Executive Summary: ISDH's Obligation Is To Deny WWHA's Application.

The application of the Texas abortion chain, WWHA, must be denied per I.C. 16-21-2-11(a)(1) and 40 I.A.C. 26-2-5(1) because WWHA's history of violations at all of its abortion clinics demonstrates that it is "not of reputable and responsible character," and WWHA's application contains evidence that it is on course to mirror the illegal operations of the Women's Pavilion in regards to its administering of RU486. That WWHA will not comply with Indiana's laws is substantiated by its past history of significant violations in other states as well as the Texas applicant's brazen choice for the same "Administrator" who operated the Women's Pavilion during the numerous violations of the law cited herein, including the systematic denial

of informed consent to scores of Indiana mothers.¹ This reckless decision is exacerbated by the plans of WWHA to utilize an itinerant physician with no support system in place in South Bend, a point recently raised by local physicians (discussed below). A reasonable presumption, then, is that WWHA will not comply with Indiana's laws. If the Indiana legislative mandates are to matter, such as I.C. 16-21-2-11(a)(1), and, if 40 I.A.C. 26-2-5(1) is to have any utility, WWHA's application must be denied.

For ISDH to approve the Texas-based abortion clinic would impose great cost on the citizens of Indiana – hundreds of thousands of dollars on surveys and enforcement actions, it would greatly increase the violations of Indiana's laws (which are currently not occurring at all in Northern Indiana). Additionally, as transcribed at a County Council meeting last week, emergency rooms and OBGYN offices will be taxed dealing with the complications that result from the medical abortion process, including being forced to negotiate the treatment when there is still a live unborn child as a result of a botched medical abortion. Based on the local physicians' experience with Women's Pavilion, the circumstances surrounding WWHA's application, with only medical abortions being performed and the itinerant abortionist being out of town, the impact on the South Bend medical community could be significant.

ISDH's approval of WWHA's application would likewise victimize Indiana mothers who are currently being assisted by the numerous crisis pregnancy organizations. Mothers facing a crisis pregnancy in Northern Indiana have a plentitude of complete resources readily available to them such as adoption, medical, financial, or legal assistance, and shelter from homelessness or domestic violence, to support them and their unborn child. Moreover, for the mother who still desires an abortion, there is no undue burden placed on her as she can get an abortion at Planned Parenthood of Merrillville, Indiana, which is only 65 miles from South Bend, and she can consult with Planned Parenthood of Mishawaka, a couple miles from South Bend.

Accordingly, given the legal deficiencies of WWHA's application as well as the costs and other harms that would be inflicted on Indiana's citizenry, approval of WWHA's application would be arbitrary, capricious, and an abuse of discretion.² An abortion clinic in South Bend, to be had at such great expense, when it is not needed by the mothers in South Bend, is simply not mandated by the law. There is no legal basis – neither constitutionally, statutorily, or

¹ At a minimum, WWHA's hiring of the Women's Pavilion's past "Administrator" demonstrates a disregard for its reputation as well as its responsibility to comply with Indiana laws. Even if WWHA argues that it does not intend to systematically violate Indiana's laws governing abortions as the Women's Pavilion did, its negligent choice of Women's Pavilion's "Administrator" shows that WWHA is not "responsible."

² By referencing the "arbitrary, capricious and abuse of discretion" rule, the undersigned is using shorthand for the full standard of obtaining judicial relief when a person has been prejudiced by an agency, which, in this case would entail showing that the ISDH's decision was (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (4) without observance of procedure required by law; or (5) unsupported by substantial evidence. I.C. § 4-21.5-5-14(d). To be clear, this would not be the only relevant standard for seeking the relief available to the class of injured Hoosiers, but it will play a role.

regulatorily – that compels ISDH to approve WWHA’s application. Indeed, to approve of WWHA’s application, under these conditions, would also signify ISDH’s refusal to take note of the Indiana legislature’s previous finding that the protection of unborn children is a compelling state interest. Thus, there is no rational basis for ISDH to spurn the desires of the Indiana citizenry by obligating Indiana taxpayers to fund the regulation of another violation-prone abortion clinic.

II. ISDH’s Past Performance in Regulating the Women’s Pavilion in South Bend Undercut the Laws of Indiana and Proved to be Overly Costly and Ineffective.

Acknowledging that the ISDH has experienced turnover in personnel over the past year, including at its helm, the following recitation of history is provided regarding the ISDH and its relationship with the Indiana pro-life groups and individuals that are taking a stand against the licensing of lawless abortion clinics/abortionists. It is also highly relevant to the current inquiry and the necessity of the applicant to be “of reputable and responsible character.”

The entirety of the laborious history between Women’s Pavilion and ISDH need not be reiterated here; a summary of that recent history will suffice to make the necessary point that Indiana cannot afford to re-visit this scenario. The surveys by ISDH, stretched out to be conducted only biennially (much to a rogue abortion clinic’s advantage), continually led to voluminous citations against Women’s Pavilion, including informed consent violations and practices that were harmful to a woman’s health. (See 2010, 2012, and 2014 Survey Reports) These then led to enforcement actions, *i.e.*, agreements, handled by ISDH personnel and sometimes the Attorney General’s office. Furthermore, during this same time period, Women’s Pavilion was prosecuted for failing to comply with statutory reporting violations, taxing local prosecutors and Indiana’s judicial system.

This significant waste of taxpayer monies, due to ISDH’s inappropriate licensing of irresponsible applicants, is only part of the damage done to Indiana’s citizenry.³ Mothers, presumptively protected by the laws in place, are also harmed when abortionists and abortion clinics are able to take advantage of ISDH’s willingness to license clinics that are not “reputable and responsible.” It was three years ago to the day (and just months after the 2014 Survey Inspection) that the undersigned was hired to enforce Indiana’s informed consent law against Women’s Pavilion, given the complaint of a mother who was given the first pill of the medical abortion process without informed consent. The affidavit of that mother who is still mourning to this day is attached hereto as Exhibit 1 and demonstrates what vigilant pro-lifers assumed was the case in 2014 -- that Women’s Pavilion was performing medical abortions without the informed consent of the mothers seeking counseling on abortion.

That the Women’s Pavilion’s violation of the informed consent law was systemic was confirmed with more evidence procured by the vigilante efforts of TLC Advocates. For

³ The enforcement of the pro-life laws of Indiana in regards to abortion clinics was placed solely with ISDH who “shall make all . . . inspections in response to an alleged breach of this chapter or rules adopted under this chapter.” I.C. 15-21-1-10(a); see also I.C. 16-21-2-2.5; see also I.C. 16-21-2-2.5, 2.6.

instance, a statement by one of TLC Advocates, provided to the ISDH, testified to a telephone conversation with the Women's Pavilion staff wherein the administration admitted that they would perform a medical abortion without informed consent. When the ISDH failed to act upon this complaint, another TLC Advocate telephoned Women's Pavilion and audiotaped the conversation wherein the Women's Pavilion administration again admitted that they performed medical abortions without Indiana's informed consent laws. Even with this accumulating and momentous evidence, ISDH did not act, and the number of informed consent violations grew.

This recalcitrance by the ISDH to enforce the informed consent law, and ISDH's intentions to settle past violations of the Women's Pavilion – such intentions being normal for ISDH but being discovered only through a document request⁴ – inspired a coalition of Indiana pro-life groups to launch the “Answer the C.A.L.L.” campaign on Ash Wednesday of 2015. (See 2/17/15 Press Release as Exhibit 2, attached hereto) Thousands of signatures were gathered, protests were held, the legal case to force the enforcement of Indiana's laws was prepared, and the media was kept informed. Additionally, the vigilante efforts of TLC Advocates, in gathering evidence of the mounting informed consent violations, continued and was submitted to ISDH.

In June of 2015, the ISDH finally acted, conducted a Survey Inspection of Women's Pavilion, and found 10 out of 10 violations in the Women's Pavilion files they inspected.⁵ These findings, the resulting validation of TLC Advocates' complaints, and ISDH's refusal to renew Women's Pavilion's license is attached hereto as Exhibit 3. It is unclear why ISDH waited so long to react to the illegal operations of Women's Pavilion, in the face of very compelling evidence – whether the ISDH is understaffed or simply unmotivated to enforce Indiana's pro-life laws. It is also unclear why ISDH did not immediately shut down Women's Pavilion and penalize them heavily as they are authorized to do. (See I.C. 16- 21-3-1(6); see also I.C. 16-21-3-2, 16-21-2-2.6, 16-21-1-10)

Accordingly, in the absence of ISDH enforcing the revocation of Women's Pavilion's license, the coalition of pro-life constituents referenced above dutifully solicited evidence from mothers who were abortion clients of Women's Pavilion, and over 50 complaints of informed consent violations were submitted to the ISDH. Sadly, as set forth in the correspondence constituting Exhibit 4, attached hereto, the ISDH not only permitted Women's Pavilion to

⁴ The groups represented by this notice intend to submit a records request for the entirety of the file accumulated in response to WWHA's application. Because ISDH is still collecting documents, the undersigned prefers to wait until all documents to be collected are collected. To make a showing of a lack of due diligence concerning the “reputable and responsible” determination and to make the “arbitrary and capricious” showing, the entirety of the file will be necessary. In the event that the ISDH denies WWHA's application, prior to the records request referenced herein, no such records request will be necessary.

⁵ The fascinating nature of the ISDH's findings in response to the TLC Advocates' complaints – that there was not one patient file in compliance with the informed consent law – cannot be overstated. It validates all of the complaints of the TLC Advocates and shows a blatant disregard of Indiana's laws, even those that carry a criminal penalty. This brazen-ness by the Women's Pavilion “Administrator” should be an absolute bar to licensing. WWHA's choice of the same “Administrator,” and WWHA's own voluminous record of violations, would be enough evidence for a reasonable person to deny WWHA's application.

continue operating without penalty, but it would not process further complaints by the TLC Advocates on the grounds that they were “repetitious.” As if a rapist can only be prosecuted for one of many rapes, or a murderer prosecuted for only one of many murders, or a thief charged with one of many thefts, this rationale is so bereft of reason and justice that it can only point to the desire of ISDH to look-the-other-way in the face of criminal wrongdoing by an abortion clinic and exculpate a systematic illegal abortion operation doing great harm to Indiana women.⁶ Pressure on ISDH remained constant including protests and education of the public. (See Handbill and Press Release, Exhibit 5, attached hereto)

Finally, as a matter of background, lest the ISDH point to the revocation of the Women’s Pavilion license as a response to the above allegations of malfeasance, the history of the ISDH for at least the past decade – as demonstrated by the survey reports and “enforcement actions” that followed – was for the decision-makers at ISDH to fail to hold Women’s Pavilion accountable for their transgressions against the women of Indiana, and to enable Women’s Pavilion to continue their systemic violations as long as Women’s Pavilion would sign-off on an agreement to “do better next time.” Summing up the background, then, the citizens of Indiana have been cheated from having a regulatory body willing to enforce Indiana laws, and the ISDH has left a trail of frustrated constituents and a landscape of harmed women who were victims of an abortion clinic determined to undermine the pro-life laws of the Indiana legislature.⁷ Those constituents, along with the other pro-life groups, state representatives, and medical professionals are again standing at ISDH’s door asking for ISDH to make the proper findings and render the proper – legal – decision regarding WWHA’s application for an abortion clinic.

III. WWHA Cannot Show, As Required, That It Is “Reputable And Responsible.”

With so much at stake in approving an abortion clinic that can meet the health and safety standards of Indiana law, it was logical and necessary for the legislature to require that abortion clinic applicants submit an application “showing that the applicant is of reputable and responsible character.” I.C. 16-21-2-11(a)(1); 410 I.A.C. 26-2-5(1). It is a legitimate threshold because non-reputable and irresponsible abortion clinics will by nature inflict harm on Indiana citizens and unfairly impose significant costs on the taxpayers. And note that this threshold is stated in the conjunctive – it requires that the applicant is both “reputable *and* responsible.” If the applicant is missing either one of these character attributes, the application must be denied. As the evidence cited herein demonstrates, WWHA is a far cry from meeting the “reputable and responsible” requirement, and, accordingly, to approve WWHA’s application for an abortion clinic would be arbitrary, capricious and an abuse of discretion.

⁶ If not for the extraordinary vigilante efforts of the TLC Advocates, the persistence of the pro-life constituents, the extraordinary readiness of TLC Legal to bring suit, and the fortitude of the Attorney General’s office once all the above was set in motion, there is no reason to conclude that Women’s Pavilion would not be operating still today with no regard to the Indiana laws concerning informed consent.

⁷ In line with the ISDH’s treatment of the TLC Advocate’s complaints regarding the harm being done to the clients of the Women’s Pavilion, the ISDH took an adverse position to the plans of The Life Center to install a Safe Haven Baby Box on-site of The Life Center, next to the Women’s Pavilion.

The impossibility of WWHA showing it is “of reputable and responsible character” is threefold. First of all, public records and public discussion show that WWHA’s character is not reputable and it is objectively very poor in terms of compliance with abortion clinic regulations. Second, WWHA’s designation of “the person to be in charge of the institution,” per I.C. 16-21-2-11(b)(4), choosing on its application the same “Administrator” that operated the Women’s Pavilion during its reign of systematic illegal operations – demonstrates that WWHA is not concerned with its reputation and could not be more irresponsible in showing its commitment to following Indiana law. Thirdly, WWHA’s response to the legitimate concerns of Indiana citizens – the medical care to be delivered and the availability of follow-up to compensate for the risk of complications, is non-existent.

A. ISDH Must Deny WWHA’s Application Because WWHA Is Not In The Least Bit “Reputable.”

To be of reputable character is to enjoy good repute and be held in esteem. WWHA does not enjoy that attribute. Indeed, WWHA is known as the abortion clinic chain with a notoriously poor compliance record. There simply is too much noise about them for it not to be true, and, ultimately, “you are what your record says you are.”⁸ An article by Abby Johnson, a former abortion clinic worker in Texas, tells it like it is in a very recent report, based on the inspection reports and statements by witnesses with first hand knowledge. (See 10/27/17 “Whole Woman’s Health Exposed, /AbbyJohnson/ 2 0 1 7/ 9 / 6 / Whole-Womens-Health-Exposed, attached hereto as Exhibit 6) The article itself incorporates 50 pages of government inspection reports on which the article is based. (*Id.*) The pervasiveness of WWHA’s obliquitous reputation was also acknowledged by the recent headlines of the WASHINGTON FREE BEACON, a national news agency: “Texas Abortion Clinics Marred with Health, Safety Issues, Inspection Reveals.”⁹ (See article attached hereto as Exhibit 7)

These recent articles are not rhetorical pieces – they are based upon and motivated by the startling inspection reports and testimony. “The documents show a widespread problem of health violations at WWH clinics.” (*Id.*) A look at some of the underlying documents shows that these Texas clinics by WWHA are repeat offenders and not reputable in any sense of the word. (See, e.g., 12/29/15 Inspection Report for WWHA San Antonio, TX, attached hereto as Exhibit 7.1; 12/02/15 Inspection Report for WWHA McAllen, TX, attached hereto as Exhibit 7.2; Exhibit 6, *supra*). Furthermore, it is something that has been going on for a long time as the attached article from 2011 demonstrates, citing the fines against WWHA in Austin and McAllen. (See 12/1/11 “Over \$83,000 in Fines Assessed in Texas for Illegal Dumping of Aborted Baby Remains,” Exhibit 8 attached hereto; see also Exhibit 6, *supra*, attached hereto)

The unflattering reputation of WWHA is something that has been noticed by many of the

⁸ This quote, which is one of the poignant truisms by NFL Coach Bill Parcells, as well as other dandies, can be found at http://www.azquotes.com/author/11297-Bill_Parcells.

⁹ The timely article was posted by *Charles Fain Lehman* On October 27, 2017, and is found at <http://freebeacon.com/issues/texas-abortion-clinics-marred-health-safety-issues-inspection-reveals/>.

watchdog organizations. As THE DAILY CALLER NEWS FOUNDATION commented: “[a] slew of Whole Woman’s Health (WWH) abortion clinics miserably failed inspection reports between 2011 and 2017,” and citing to the Free Beacon article referenced above. (See THE DAILY CALLER, “Abortion Clinics Are Crawling With Dirty Health Violations, Report Finds,” by Grace Carr, 10/27/17, attached hereto as Exhibit 9) The sloppiness negatively effects women’s health as set forth in the May 19, 2014 article by Cheryl Sullenger, “Why Should Abortionists have Admitting Privileges? Look at these Botched Abortions at Just One Clinic,” found at LifeNews.com. (See Exhibit 10 attached hereto)

And it is not just the Texas clinics of WWHA. The other clinics in Maryland and Illinois have similar violations problems as summarized in Exhibit 11, attached hereto. (Excerpts from chart found at unsafereport.org/wp-content/uploads/2016/12/Unsafe-Chart.pdf) Violations have been a consistent theme of WWHA’s operations for a while, as summarized by Operation Rescue, attached hereto as Exhibit 8 (12/1/2011 “Over \$83,000 in Fines Assessed in Texas for Illegal Dumping of Aborted Baby Remains”)¹⁰ Accordingly, when the volume and depth of the violations, along with their consistency from state to state, are considered, it would be irrational to conclude that WWHA is reputable.

Lastly, WWHA went to extreme lengths in its application to defy the “reputable” requirement by appointing as its “administrator,” Liam Lynn Morley (see Exhibit 12, attached hereto), the same administrator who managed the Women’s Pavilion -- a habitual offender of the laws of Indiana which cost taxpayers and the abortion mothers who sought Women’s Pavilion’s assistance.¹¹ As reported by the South Bend Tribune, “Liam Morley is listed as the proposed clinic’s administrator. She was an employee for several years at the clinic Klopfer ran (See Exhibit 13, attached hereto). She stated in more than one interview that neither she nor the group she heads – “Pro Choice South Bend” – was involved in the effort to launch a clinic in South Bend. (See, e.g., *id.*) Clearly, then, it is WWHA that sought-out Ms. Morley and would have been aware of her past experience with Women’s Pavilion when the clinic was engaging in a culture of illegality. Hardly the pick any reasonable person would make if that reasonable person was trying to satisfy the “reputable” requirement in order to be licensed.

The fact that WWHA chose the Women’s Pavilion’s operator to be its administrator validates the concern of the local medical community that WWHA fits the same compliance profile as Women’s Pavilion. (See Exhibit 13, attached hereto, WSBT News Reporting on 12/6/17 County Council Meeting) That makes the point of Northern Indiana family physician Laura McGuire all the more poignant when she stated at the Council Meeting that she’s “concerned about the former South Bend abortion clinic, which was shut down after failing to

¹⁰ The article can be found at www.operationrescue.org/archives/over-83000-in-fines-assessed-in-texas-for-illegal-dumping-of-aborted-baby-remains/

¹¹ Searches on social media by the TLC Advocates confirm that this is the same “Lynn Morley” or “Liam Lynn Morley” that operated the Women’s Pavilion for the last several years of the clinic’s operations (see Exhibit 12a, attached hereto), during which the TLC Advocates accumulated evidence – including an audio recording – of the Women’s Pavilion’s practice of bypassing the informed consent law.

procedures to the state, and we know that there is an organization here [WWHA] that has the same kind of profile as Dr. Klopfer" (*Id.*) During the two hour meeting, a number of other members of the medical community recited their concerns of the shaky reputation of WWHA.

The violation-prone operations of the Texas group are an even more serious concern to the medical community because of the lack of a plan to deal with complications or recovery of the patients of WWHA's circuit doctor, Dr. Jeffrey Glazer. (See *id.*, Exhibit 13, attached hereto; Exhibit 15, attached hereto, 12/7/17 S.B. Tribune reporting "Group of Doctors Speak Against South Bend Abortion Clinic") The medical community in Northern Indiana complained that WWHA would "burden the medical community" and that "local hospitals will be compelled to provide treatment to women with complications from medication-induced abortions." (Exhibit 15, attached hereto) The doctors went into detail over the two hour process describing the complications that do arise on a statistical basis and how in the past that they have been forced to deal with them. They also lamented that a circuit doctor, likely in South Bend for one day per week, and continuously traveling, would not be available for any follow care, and was not a good match for WWHA's plan of medical abortions. Given WWHA's horrid compliance record, and the fact that their proposed physician is commonly traveling between his practice in Indianapolis and two other states, this is an authentic issue that deserves an authentic response.

Part of the reason why the clients represented by this letter, and the undersigned, waited until now to provide this legal opinion to ISDH is that we were waiting to see how or if WWHA would respond to any of the inquiries or criticisms regarding their application to locate in South Bend. Instead of responding with evidence that WWHA is reputable and responsible, WWHA has only responded with political rhetoric. The legitimate concerns of Indiana citizens regarding WWHA's compliance problems, the similarities of WWHA with Women's Pavilion, and the health and safety concerns raised by WWHA's application was met with venomous political attacks:

- As part of the South Bend Tribune's reporting on the application, October 14, 2017, the President and CEO of WWHA stated in an email attributed to her: "It is our commitment to go into places that are underserved and where women have suffered because so many clinics have shuttered due to continued political interference. South Bend women and families deserve access to high quality abortion care services..." (Exhibit 14, attached hereto)
- A couple weeks after that statement, the President and CEO of WWHA issued another political motivation to their application: "As we witness ongoing attempts by the Trump administration to bully and block women who need abortion care, I'm proud to announce that we are expanding our healthcare work, to open . . . the clinic in South Bend as soon as we can. . . to combat abortion stigma." (Exhibit 16, attached hereto, WNDU coverage of WWHA application)¹²

¹² In that same WNDU coverage, the quote of Shelly Dodson, Center Director of All-Options in Indiana, shows the mistaken political motivations of WWHA's continuous diatribe against President Trump, Vice President Pence, and the pro-life legislature of Indiana: "We are thrilled that Whole Woman's Health

- In response to the complaints of the medical community the WWHA responded with this statement: “[A]ccess to quality abortion services has been continually decimated in Mike Pence’s Indiana communities, such as South Bend, and ... we are committed to improving people’s lives by providing access to the best medical care, which include the full range of reproductive health services for women.” (Exhibit 15, attached hereto)
- WWHA has not provided a response to the mounting concerns by the South Bend medical community, and they declined to interview on that topic or any of the other topics such as the financial burden on taxpayers given its similarity to the Women’s Pavilion debacle or the fact that mothers are getting the services they need in South Bend, the president and CEO of WWHA instead declared generically that WWHA clinics are “committed to improving people’s lives by providing access to the best medical care, which included the full range of reproductive health services for women.”¹³ (Exhibit 13, attached hereto)

It stands to reason then that the concerns of the elected officials, the Northern Indiana pro-life community filling the needs of pregnant mothers, the medical community in South Bend have legitimate concerns about the “reputation” of WWHA and that reputation cannot be sufficiently rehabilitated with so much water under the bridge. The ISDH is left with no choice except to deny the application of WWHA on the basis of WWHA’s horrid compliance record, its similarities with the costly Women’s Pavilion debacle, its decision to hire the administrator of Women’s Pavilion during its lawless rein that led to its closure, and the fact that WWHA’s plan of a circuit doctor is problematic in the dispensation of medical abortions – which occurs out of the abortion clinic a day or three after the initial pill – and will impose a significant cost on the medical community.

There is no legal requirement, Constitutional or otherwise that requires ISDH to do anything other than to deny the Texas group’s application. Even if the “undue burden” standard was relevant here, and it is not, no undue burden exists in Northern Indiana for a mother seeking an abortion to get her abortion counseling within a couple miles, and, if an abortion is still desired, only travel 65 miles. Accordingly, WWHA’s disrepute, and there being no undue burden, for the ISDH to anything other than deny WWHA’s application would be arbitrary, capricious and an abuse of discretion.

will be opening a clinic in South Bend, and look forward to having another provider to refer clients to in Indiana, reducing their need to travel out of state to find the abortion care they need.” (Exhibit 16, attached hereto) It is false and misleading to say that abortion-minded mothers need to go out of state for abortions services when they can travel a couple miles to the Planned Parenthood of Mishawaka, for abortion counseling, or they can go straight to the Planned Parenthood of Merrillville for a medical or surgical abortion.

¹³ WWHA’s generic statements do not constitute evidence of “reputation,” and given the factual record of WWHA’s performance at its number of clinics, the generic statements are completely false. Again, “you are what your record says you are.” (See *supra* note 8)

B. ISDH Must Deny WWHA's Application Because WWHA Is Not "Responsible."

Even if the ISDH found WWHA to be "reputable" – an improbable hypothetical – WWHA does not meet the "responsible" criterion as part of I.C. 16-21-2-11(a)(1) and 410 I.A.C. 26-2-5(1). "Responsible" is not an ambiguous term, and is often defined by having "obligations" or "accountability," and "liable to be called on to answer." And to state again, both criterion, "reputable" and "responsible," must be met despite the similarities between the two requirements. To the extent that the evidence showing WWHA is not "reputable" is the same as the evidence to show that WWHA is not "responsible," the relevant portions above will be referenced instead of being repeated in their entirety.

For many of the same reasons cited above, WWHA falls woefully short of meeting the "responsible" requirement. There are hundreds of pages of violations and penalties demonstrating how irresponsible WWHA is. (See *supra* pp. 5 - 8) Would WWHA dare to say that its record of violations and penalties constitutes "responsible" conduct? WWHA would condemn itself with its own words if such a statement were made; in WWHA's instance, it is best to remain silent and plead the 5th. Simply put, no reasonable person would argue that WWHA's compliance record and willingness to comply with the law demonstrate "responsible" character.

WWHA's irresponsibility is further shown by the choice of its "Administrator," choosing the former administrator of the Women's Pavilion – the same administrator whose tenure encompassed the years of illegally dispensing RU486 without informed consent. (See *supra* pp 2 - 5) The charges levied against Women's Pavilion were very serious, especially the statutory rape charges and the informed consent violations that bear criminal penalties. To hire the same Administrator who was just one of the few staff members of Women's Pavilion during this time sends a clear message of severe irresponsibility.

WWHA demonstrates its lack of "responsibility" by concocting a business model with an absentee "Medical Director," the doctor/abortionist, who will likely not be in town or available when his patients take the second pill of the chemical cocktail known as RU486, which causes the patient to undergo contractions and expel the fetus.¹⁴ Even using the figures proposed by the abortion industry (which are not supported by the experiential data collected by watchdog groups), the complication rate for medical abortions is at 5.2%.¹⁵ Accordingly, is it responsible

¹⁴ Mifepristone (mifeprex) is the first pill of the RU486 pill process and the first pill kills the unborn child by cutting-off the child's nutrition, and, then, the second pill, Misoprostol, taken at home by the mother causes her to undergo contractions in order to expel her child wherever she happens to be at that time. For a description of the history of RU486, and the process used by the abortion industry (albeit from a pro-life perspective), see www.40daysforlife.com/2017/12/08/ru-486/.

¹⁵ "Incidence of Emergency Department Visits and Complications After Abortion" by Advancing New Standards in Reproductive Health ("ANSIRH"), Ushma D. Upadhyay, PhD, *et. al.*, published in OBSTETRICS & GYNECOLOGY: January 2015 - Volume 125 - Issue 1 - pp. 175–183, p.1, found online at http://journals.lww.com/greenjournal/fulltext/2015/01000/Incidence_of_Emergency_Department_Visits

to devise a business model using a circuit doctor who will unlikely not be available for follow up when the mother takes the second pill at home or wherever she is at that time? The complication prone medical abortion process screams for an ever-ready doctor so that every complication does not end up in the emergency room. An agreement with a local doctor who has admitting privileges to a local hospital does not reduce this need for immediate care by mothers experiencing complications from the second pill.

Since, complication rates for medical abortions are much higher than surgical abortions (again, with medical abortions being 5.2%),¹⁶ is WWHA behaving responsibly when it has requested, through its attorneys, for the waiver of certain abortion clinic requirements so that they do not have to adhere to all of the laws on the books for such clinics? should there not be more of regulatory imposition on WWHA's proposed business model in order to protect Indiana mothers? Do not Indiana citizens, not interested in a medical problem being imposed on them, deserve more than political rhetoric (see *supra* pages 8-9) in response to the complications that arise from medical abortions? WWHA's request and business model are irresponsible.

How can WWHA claim that they are "responsible" when its proposed business model imposes emergencies and immediate-care-questions on others, especially considering that most of those others do not want to handle it. This was a common refrain of the medical community in South Bend as they brought their concerns to the County Council. (See Exhibits 13, 14, and 15 attached hereto) The medical profession in South Bend has sounded the alarm, and WWHA can only muster political rhetoric to justify its business plan. Is that responsible? Even if the complication rates are as low as the abortion industry says they are for medical abortions, 5.2 %, there still will be a significant impact on the medical community of South Bend unless there is a plan in place to deal with the emergencies and the post-RU486 dispensation. Accordingly, since there is no plan in place beyond an "agreement" with a doctor in the area who has admitting privileges, which of course does not lessen the impact on the local medical community, WWHA's plan is irresponsible.

WWHA's inability to demonstrate that it is "responsible" in the face of such serious matters demands that the ISDH deny WWHA's application. The concerns of the legislature which drafted the legislation requiring clinic applicants to be "reputable and responsible" should be followed. The concerns of the individual elected officials – both state and federal – should be listened-to given that their position enables them to see that mothers are being cared-for in Northern Indiana, and abortion services are still available to those who desire them. The Northern Indiana citizens who do not want their taxes spent on a violation-prone, out-of-state

[and.29.aspxe.](#)

¹⁶ *Id.* at p. 1. Although this study was done by the abortion industry, it still admits that "complication rates are underestimated by low follow-up rates." (p. 1) Watchdog groups claim that only one out of 10 complications are reported. See www.40daysforlife.com/2017/12/08/ru-486/. That certainly has been the experience of the local watchdog groups like TLC Advocates and 40 Days for Life, South Bend, who have witnessed firsthand that the complication rate for these medical abortions is much higher than reported by the abortion industry. (Cf. Exhibit 1, attached hereto, describing the regret of a mother who experienced a medical abortion)

organization should be taken seriously. And last, but not least, the medical community in South Bend who do not want to be responsible for the complications of WWHA provide a relevant and persuasive reason for denying WWHA's application. What is irrelevant and demonstrative of the irresponsibility of WWHA is treating the matter as a political matter deserving only of political rhetoric instead of real facts responsive to the issues at hand.

The ISDH is left with no choice except to deny the application of WWHA on the basis of WWHA's horrid compliance record, its similarities with the costly Women's Pavilion debacle, its decision to hire the administrator of Women's Pavilion during its lawless rein that led to its closure, and the fact that WWHA's plan of a circuit doctor is problematic in the dispensation of medical abortions – which occurs out of the abortion clinic a day or three after the initial pill – and will impose a significant cost on the medical community.

As stated above, there is no legal requirement, Constitutional or otherwise that requires ISDH to do anything other than to deny the Texas group's application. Even if the "undue burden" standard was relevant here, and it is not, no undue burden exists in Northern Indiana for a mother seeking an abortion to get her abortion counseling within a couple miles, and, if an abortion is still desired, to travel 65 miles. Accordingly, WWHA's inability to meet the "reputable and responsible" requirement, and the "undue burden" standard being inapplicable, the ISDH would prejudice Northern Indiana citizens and the medical community by granting WWHA's application, and, accordingly, granting the application would be (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (2) contrary to constitutional right, power, privilege, or immunity; (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (4) without observance of procedure required by law; or (5) unsupported by substantial evidence. (I.C. 4-21.5-5-14(d))

IV. Conclusion

With new leadership at ISDH, there is an opportunity here for that new leadership to build a trusting relationship with the constituents here in the Northern portion of the state. These same constituents had their faith in ISDH severely shaken after years of licensing the lawlessness of the Women's Pavilion. ISDH's lack of zeal to enforce the laws against the Women's Pavilion, and ISDH's evasive conduct in prosecuting and shutting down an operation that admitted it was systemically violating the criminal laws of the state related to informed consent.

We are also calling on the Attorney General's office and the Governor's office to do their part in ensuring that Indiana's citizens are heard and that the ISDH does not abuse its discretion, go outside the existing law and evidence, and inflict great harm on our community in Northern Indiana. We note that the current Attorney General, Curtis Hill, Jr., has stated that he is "an advocate for the people." We will call him to be just that. We will bring this issue to the populace, elected officials, the ISDH and the courts. We plan on continuing to promote a great deal of attention on this issue through the media, social media, and public protests.

We will be there to encourage and support your efforts to do the just and legal action necessitated by the law and facts governing this matter. Lest there be any concern over a WWHA lawsuit when its application is denied, consider that a blessing. The opportunity to do

justice in this instance is well worth the time, energy, and expense. The entirety of the international pro-life community would applaud and support your effort to dispel current myths regarding medical abortions and educate the world with the salient truths concerning the physical effects and complications, the psychological effect on mothers, and the deplorable state of compliance with the current – yet insufficient – regulations governing the medical abortion industry.

Please feel free to contact me regarding any of the above, and I will keep you informed of the growing number of similarly situated clients pleading with ISDH to Answer the C.A.L.L.

Sincerely,

A handwritten signature in black ink that reads "Shawn F. Sullivan". The signature is fluid and cursive, with the first name "Shawn" and last name "Sullivan" clearly distinguishable.

Shawn F. Sullivan, IN Bar No. 21472-71
S. F. SULLIVAN, ATTORNEY AT LAW, LTD

c. The Honorable Curtis T. Hill, Jr.
Indiana State Attorney General
302 W. Washington St, 5th Floor
Indiana Government Center South
Indianapolis, IN 46202
Fax: (317) 232-7979

The Honorable Eric J. Holcomb
Office of the Governor
200 W. Washington St.
State House Room 206
Indianapolis, IN 46204-2797
Fax: (317) 233-3378

EXHIBIT LIST

- Exhibit 1: M [REDACTED] Witness Statement
- Exhibit 2: "Answer the C.A.L.L." campaign (2/17/15) and press release
- Exhibit 3: TLC Advocates' complaints upheld by ISDH
- Exhibit 4: Letters to and from state regarding lack of prosecution of Women's Pavilion
- Exhibit 5: Handbills and press release protesting ISDH handling of Women's Pavilion
- Exhibit 6: 10/27/17 "Whole Woman's Health Exposed" by Abby Johnson
- Exhibit 7: Article in WASHINGTON FREE BEACON re: violations at TX clinics
 - Exhibit 7.1: Violation reports for WWHA clinic in San Antonio, TX
 - Exhibit 7.2: Violation reports for WWHA clinic in Macallum, TX
- Exhibit 8: Article re: fines against WWHA clinics in TX
- Exhibit 9: Article in Daily Caller re: violations of WWHA clinics
- Exhibit 10: Article in LifeNews re: botched abortions at WWHA in Austin
- Exhibit 11: Chart showing IL and MD violations at WWHA
- Exhibit 12: Application and identification of the "Administrator"
- Exhibit 13: WSBT coverage of doctors protesting proposed WWHA clinic in South Bend
- Exhibit 14: SB Tribune reporting on WWHA's plans to open abortion clinic in South Bend
- Exhibit 15: SB Tribune reporting on medical communities' complaints regarding WWHA
- Exhibit 16: WNDU coverage of WWHA's intentions to do clinic in South Bend

I, Mandy [REDACTED]:

EXHIBIT 1
Legal Opinion to ISDH

1. On November 28, 2014, I went to the Women's Pavilion for my counseling appointment.
2. I was there for counseling regarding an abortion, but on my way into the Women's Pavilion, I talked to a woman on the sidewalk by the name of Ellen Master. She presented alternatives to abortion, such as adoption, and offered me financial, legal, and medical assistance to eliminate the pressure on me to have an abortion.
3. I went inside to my counseling appointment, considering what Mrs. Master had told me. But during the counseling visit the abortionist asked me to sign-off on some paperwork and gave me a pill.
4. Upon my exit from the Women's Pavilion, I talked again to Mrs. Master, and, although I wanted to consider these options, I informed Mrs. Master that it was too late because the abortionist had already given me the abortion pill that I took in his office.
5. This all occurred over a two hour period during my first visit to the abortionist on November 28, 2014.

Mandy [REDACTED]
Mandy [REDACTED]

12/1/15 Date

Natural Family Planning • Theology of the Body Training • Natural Family Planning
• A Haven for Healing • Health-First • Life Support • Facts-First • Silent No More •
Health-First • TLC Advocates • **Life Center** • A Haven For Healing • Health-First
• Facts-First • Life Support • • Holy Family Adoption Agency •
Natural Family Planning • 40 Days For Life, South Bend
• Holy Family Adoption Agency • Health-First • Silent No More • TLC Advocates •
TLC Advocates • Health-First • Natural Family Planning • Facts-First • Life Support

Answer the **C.A.L.L.** Campaign

Citizens Against Licensing Lawlessness

For Immediate Release

Contact: Shawn Sullivan, Esq.
SullyatLaw@sbcglobal.net
Cell: (574) 286-7860
Fax: (574) 233-7862

State Health Department, Citizen Group Call for Closure of South Bend Abortion Clinic

Summary of Release: Concerned citizens and representatives of the non-profit entities located at the Life Center in South Bend, which is next to the abortion clinic, are initiating a campaign "Answer the C.A.L.L. (Citizens Against Licensing Lawlessness)." According to the spokesperson for Answer the C.A.L.L., Shawn Sullivan, Esq., the campaign is in response to the continued lawlessness of Dr. Ulrich "George" Klopfer. In just the past few months, the entities at the Life Center have reported violations to the Indiana State Department of Health (ISDH), and the ISDH just recently filed a complaint against the abortion clinic seeking a revocation of its license. The ISDH's complaint is based on a multitude of violations that turned up from ISDH's survey of the abortion clinic in late October 2014. Dr. Laura McGuire, M.D., after reviewing the complaint, stated that the abortionist's "practices can cause injury or even death." Adding these violations to the past five years' worth of violations, the two recent criminal prosecutions brought against Dr. Klopfer and the abortion clinic, as well as the voluminous complaints to the Indiana Attorney General's office, the Answer the C.A.L.L. campaign is demanding that public officials close the abortion clinic before something tragic occurs. Sullivan says: "Because no one concerned about the well-being of the patients and their loved ones should ignore the evidence any longer, we are specifically calling upon our public officials to immediately act to protect the public and not wait until South Bend has a disaster on its hands."

SOUTH BEND, Indiana, February 18, 2015: Representatives from several local non-profit organizations revealed today that the Indiana State Department of Health (ISDH) has asked an Administrative Law Judge to revoke the license of the South Bend abortion clinic known as the Women's Pavilion. The clinic is operated by Dr. Ulrich "George" Klopfer, The non-profits, located at The Life Center, 2018 Ironwood Circle in South Bend – adjacent to the abortion clinic – monitor the operations of the clinic and have filed complaints with the ISDH. Along with other concerned citizens, representatives from the non-profits have formed an action group called "Answer the C.A.L.L. (Citizens Against Licensing Lawlessness)." As evidence of this lawlessness, the Answer the C.A.L.L. cite the recent non-profits' complaints against the Women's Pavilion, the two recent criminal actions -- one in Lake County and the other in St. Joseph County, thousands of complaints filed with the Attorney General's office, the pending review of Dr. Klopfer's Medical License (re-scheduled for March 26, 2015), and the recent survey of the ISDH showing numerous serious violations of the state's medical rules for surgical abortion clinics.

The recent complaint by the ISDH is made up of the violations found in late October 2014, when the ISDH completed an on-site survey of the facilities. The multitude of violations all relate to patient care and safety. As Dr. Laura McGuire, M.D., a local physician, stated: "The violations set forth here are not just a matter of improper paperwork; these kinds of practices can cause injury or even death. Identical violations year after year signal a lack of genuine corrective action, and ultimately, a lack of desire to adhere to acceptable medical standards. The violations are inexcusable, and the failure to promptly remedy them is appalling." A glance at the 48 pages of violations reveals some unsettling information putting the patients at great risk:

[T]hese kinds of practices can cause injury or even death.

Dr. Laura McGuire, M.D.

1. Failure to have qualified staff overseeing the sedation (conscious sedation) of patients and failing to have qualified staff monitoring the patients in recovery;
2. Failure to have laboratory services, such as blood work and pregnancy testing, performed at a certified facility;
3. Using expired medications (from 2012) and explaining that the common medicines are on "backorder" although unable to substantiate such a claim with any documentation;
4. Failure to have an infection control plan;
5. Failure of personnel to have basic CPR training certification;
6. Failure to have immunization documentation regarding the staff that deals with the patients;
7. Failure to have an emergency plan in the event of loss of power;
8. Failure to have an evacuation plan in the event of an emergency with Dr. Klopfer stating that it "is all up here" (pointing to his head);
9. Failure to comply with numerous certification, training, and licensing of staff, including an RN without her medical license, and failing to complete annual competency assessments for professional staff;

10. Failure to develop written policies governing surgical abortion services that are designed to assure “appropriate standards of medical and patient care;”

Dr. Klopfer has refused to develop and submit a “plan of correction” for the above-listed deficiencies, despite being repeatedly asked to do so. In fact, according to Shawn Sullivan, attorney and spokesperson for Answer the C.A.L.L., a number of the violations cited in the 2014 survey were also found in the surveys done in 2010 and 2012. “This,” says Sullivan, “is what gave rise to our awareness and action campaign. The mounting evidence of Dr. Klopfer’s lawlessness would cause any reasonable person to demand the closure of such an operation before there is a disaster. This situation is a time bomb. We don’t need to wait until we have a catastrophe like that in the Kermit Gosnell case or the Brian Finkel case. We should not continue to ignore all of the signs as to where this situation is headed.” Sullivan surmised that when you consider that Dr. Klopfer had some of these same violations in 2010 and 2012, which he never corrected, and he continues to receive more citations from ISDH, and the non-profit entities monitoring Dr. Klopfer’s operations are seeing an increased disregard for the law, “it is clear that he is going to operate in this lawless fashion until he is stopped or there is horrific climax to the situation. In no other situation would we place the women of our community at such great risk and tolerate so many health and safety violations. Any restaurant with this many health violations would have been shut down many years ago.”

Sullivan noted that in addition to the “Answer the C.A.L.L.” campaign that the non-profits at the Life Center would continue to monitor Dr. Klopfer’s activities. He added that the “Answer the C.A.L.L.” campaign is designed to draw attention to the issue and “call upon our public officials and the citizens of the community to ensure that this lawless activity ceases immediately and that all licenses are revoked before it is too late.”

Bio for Shawn Sullivan: Mr. Sullivan is an attorney in South Bend and the founder and Director of the Life Center at 2018 Ironwood Circle, South Bend, IN 46615. He is a 1993 *Cum Laude* graduate of Harvard Law School, and a 1989 *Summa Cum Laude* graduate of the University of Dayton.



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

EXHIBIT 3
Legal Opinion to ISDH

June 26, 2015

REGARDING THE APPLICATION FOR LICENSE TO OPERATE AN ABORTION CLINIC:

Women's Pavilion
2010 Ironwood Circle
South Bend, IN 46635

NOTICE OF DENIAL OF LICENSE

To: Dr. Ulrich Klopfer, DO
Women's Pavilion
2010 Ironwood Circle
South Bend, IN 46635

The Director of the Division of Acute Care, Indiana State Department of Health (hereinafter referred to as "Director"), upon review and recommendation of the Abortion Clinic Licensing Program ("Program"), hereby issues this Notice of Denial of License ("Notice").

At the time of this Notice, the applicant's current licensure is pending revocation following a complaint survey conducted on June 03, 2015. During the complaint survey deficiencies demonstrating non-compliance were cited. The program believes these deficiencies provide further evidence of the clinic's inability to comply with and follow existing state law and that such behavior is an intentional and willful act.

TLC
Advocates

Based on the clinic's survey history of non-compliance, ongoing non-compliance, untimely and unacceptable plans of correction and pending license revocation, the application for licensure for the above-referenced abortion clinic (seeking licensure following the expiration of the current license on June 30, 2015) has been denied.

If you wish to seek administrative review of this action pursuant to Indiana Code § 4-21.5-3-5, you must file a petition for review within eighteen (18) days after the date of this Notice.

A petition for review must be in writing and must include facts demonstrating that:

- The petitioner is a person to whom the order is specifically directed;
- The petitioner is aggrieved or adversely affected by the order; or
- The petitioner is entitled to review under any law.

If the petition for review is not filed timely, this action becomes a **FINAL ORDER**.



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

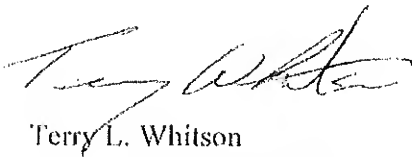
Any petition for review should be submitted in writing to:

Court Administrator
Office of Legal Affairs, #311
Indiana State Department of Health
2 North Meridian Street
Indianapolis, IN 46204-3006

Upon receipt of a timely filed petition for review, an administrative proceeding will be conducted by an Administrative Law Judge appointed by the Indiana State Department of Health.

This action does not prohibit the applicant from re-applying for licensure in the future.

Respectfully,

A handwritten signature in black ink, appearing to read "Terry L. Whitson", is written over a horizontal line.

Terry L. Whitson
Assistant Commissioner
Health Care Quality and Regulatory Commission



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

June 26, 2015

4A-07
Alyson Cox
16620 Holly Oak Dr
Westfield, IN 46074

RE: Complaint Allegation #: IN00170828

Dear Alyson Cox:

An investigation of your complaint filed with the Acute Care Division was completed on June 3, 2015 and found that your complaint was substantiated. This means the allegation(s) of your complaint was confirmed. The enclosed document is the survey report written as the result of the investigation.

When a complaint is investigated, surveyors typically interview a variety of people, review records and other documents, and make observations. Each concern of your complaint was investigated. The evidence obtained by the surveyors identified there was a violation of state requirements. These violations (deficiencies) are listed on the left-hand portion of the survey report included with this letter. The Division will review the survey findings and recommend an appropriate enforcement action.

This complaint is now closed. Should you have any questions about the report of the investigation, do not hesitate to contact us. You will need the Complaint Allegation Number identified above.

Thank you for your concern regarding the care provided to the patients in Indiana and your desire to ensure patients receive the quality care required by state regulations.

Sincerely,

John Lee, RN, MBA
Nurse Surveyor Supervisor
Program Director, Hospitals, ASC's
317/233-7487



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

June 29, 2015

4A-07
Jennifer Borek
South Bend, IN
By Email

RE: Complaint Allegation #: IN00165426

Dear Jennifer Borek:

An investigation of your complaint filed with the Acute Care Division was completed on June 3, 2015 and found that your complaint was substantiated. This means the allegation(s) of your complaint was confirmed. The enclosed document is the survey report written as the result of the investigation.

When a complaint is investigated, surveyors typically interview a variety of people, review records and other documents, and make observations. Each concern of your complaint was investigated. The evidence obtained by the surveyors identified there was a violation of state requirements. These violations (deficiencies) are listed on the left-hand portion of the survey report included with this letter. The Division will review the survey findings and recommend an appropriate enforcement action.

This complaint is now closed. Should you have any questions about the report of the investigation, do not hesitate to contact us. You will need the Complaint Allegation Number identified above.

Thank you for your concern regarding the care provided to the patients in Indiana and your desire to ensure patients receive the quality care required by state and/or federal regulations.

Sincerely,

John Lee, RN, MBA
Nurse Surveyor Supervisor
Program Director, Hospitals, ASC's
317/233-7487

(X6) DATE

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
---	---	--	---

NAME OF PROVIDER OR SUPPLIER WOMEN'S PAVILION	STREET ADDRESS, CITY, STATE, ZIP CODE 2010 IRONWOOD CIR SOUTH BEND, IN 46635
--	--

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 022	<p>Continued From page 1 29 and 30).</p> <p>Findings:</p> <ol style="list-style-type: none"> On 6/3/15 at 4:45 PM, the medical director and clinic physician #50 was requested to provide a copy of a policy/procedure for medical abortion services provided at the clinic and none was provided prior to exit. Review of the following medical records indicated: <ol style="list-style-type: none"> Patient 21 received medical abortion services on 05/01/15. Patient 22 received medical abortion services on 04/29/15. Patient 23 received medical abortion services on 05/13/15. Patient 24 received medical abortion services on 05/29/15. Patient 25 received medical abortion services on 05/26/15. Patient 26 received medical abortion services on 04/21/15. Patient 27 received medical abortion services on 05/01/15. Patient 28 received medical abortion services on 05/15/15. Patient 29 received medical abortion services on 05/27/15. Patient 30 received medical abortion services on 05/27/15. During an interview on 6/3/15 at 4:45 PM, the medical director and clinic physician #50 confirmed that no policy/procedure regarding medical abortion services was available. 	T 022		

Indiana State Department of Health
STATE FORM

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
NAME OF PROVIDER OR SUPPLIER WOMEN'S PAVILION		STREET ADDRESS, CITY, STATE, ZIP CODE 2010 IRONWOOD CIR SOUTH BEND, IN 46635		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 024	<p>Continued From page 3</p> <p>Voluntary and informed consent required; viewing of fetal ultrasound and hearing auscultation of fetal heart tone</p> <p>Sec. 1.1. (a) An abortion shall not be performed except with the voluntary and informed consent of the pregnant woman upon whom the abortion is to be performed. Except in the case of a medical emergency, consent to an abortion is voluntary and informed only if the following conditions are met:</p> <p>(1) At least eighteen (18) hours before the abortion and in the presence of the pregnant woman, the physician who is to perform the abortion, the referring physician or a physician assistant (as defined in IC 25-27.5-2-10), an advanced practice nurse (as defined in IC 25-23-1-1(b)), or a certified nurse midwife (as defined in IC 34-18-2-6.5) to whom the responsibility has been delegated by the physician who is to perform the abortion or the referring physician has informed the pregnant woman orally and in writing of the following:</p> <p>(A) The name of the physician performing the abortion, the physician's medical license number, and an emergency telephone number where the physician or the physician's designee may be contacted on a twenty-four (24) hour a day, seven (7) day a week basis.</p> <p>(B) That follow-up care by the physician or the physician's designee (if the designee is licensed under IC 25-22.5) and is available on an appropriate and timely basis when clinically necessary.</p> <p>(C) The nature of the proposed procedure or information concerning the abortion inducing drug.</p> <p>(D) Objective scientific information of the risks of and alternatives to the procedure or the use of an abortion inducing drug, including:</p> <p>(i) the risk of infection and hemorrhage;</p>	T 024		

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
NAME OF PROVIDER OR SUPPLIER WOMEN'S PAVILION		STREET ADDRESS, CITY, STATE, ZIP CODE 2010 IRONWOOD CIR SOUTH BEND, IN 46635		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 024	Continued From page 4 (ii) the potential danger to a subsequent pregnancy; and (iii) the potential danger of infertility. (E) That human physical life begins when a human ovum is fertilized by a human sperm. (F) The probable gestational age of the fetus at the time the abortion is to be performed, including: (i) a picture of a fetus; (ii) the dimensions of a fetus; and (iii) relevant information on the potential survival of an unborn fetus; at this stage of development. (G) That objective scientific information shows that a fetus can feel pain at or before twenty (20) weeks of postfertilization age. (H) The medical risks associated with carrying the fetus to term. (I) The availability of fetal ultrasound imaging and auscultation of fetal heart tone services to enable the pregnant woman to view the image and hear the heartbeat of the fetus and how to obtain access to these services. (J) That the pregnancy of a child less than fifteen (15) years of age may constitute child abuse under Indiana law if the act included an adult and must be reported to the department of child services or the local law enforcement agency under IC 31-33-5. (2) At least eighteen (18) hours before the abortion, the pregnant woman will be informed orally and in writing of the following: (A) That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care from the county office of the division of family resources. (B) That the father of the unborn fetus is legally required to assist in the support of the child. In the case of rape, the information required under this clause may be omitted.	T 024		

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
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NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

WOMEN'S PAVILION

2010 IRONWOOD CIR
SOUTH BEND, IN 46635

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 024	<p>Continued From page 5</p> <p>(C) That adoption alternatives are available and that adoptive parents may legally pay the costs of prenatal care, childbirth, and neonatal care.</p> <p>(D) That there are physical risks to the pregnant woman in having an abortion, both during the abortion procedure and after.</p> <p>(E) That Indiana has enacted the safe haven law under IC 31-34-2.5.</p> <p>(F) The:</p> <p>(i) Internet web site address of the state department of health's web site; and</p> <p>(ii) description of the information that will be provided on the web site and that are; described in section 1.5 of this chapter.</p> <p>(3) The pregnant woman certifies in writing, on a form developed by the state department, before the abortion is performed, that:</p> <p>(A) the information required by subdivisions (1) and (2) has been provided to the pregnant woman;</p> <p>(B) the pregnant woman has been offered by the provider the opportunity to view the fetal ultrasound imaging and hear the auscultation of the fetal heart tone if the fetal heart tone is audible and that the woman has:</p> <p>(i) viewed or refused to view the offered fetal ultrasound imaging; and</p> <p>(ii) listened to or refused to listen to the offered auscultation of the fetal heart tone if the fetal heart tone is audible; and</p> <p>(C) the pregnant woman has been given a written copy of the printed materials described in section 1.5 of this chapter.</p> <p>(4) At least eighteen (18) hours before the abortion and in the presence of the pregnant woman, the physician who is to perform the abortion, the referring physician or a physician assistant (as defined in IC 25-27.5-2-10), an</p>	T 024		

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
NAME OF PROVIDER OR SUPPLIER WOMEN'S PAVILION		STREET ADDRESS, CITY, STATE, ZIP CODE 2010 IRONWOOD CIR SOUTH BEND, IN 46635		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 024	<p>Continued From page 6</p> <p>advanced practice nurse (as defined in IC 25-23-1-1(b)), or a midwife (as defined in IC 34-18-2-19) to whom the responsibility has been delegated by the physician who is to perform the abortion or the referring physician has provided the pregnant woman with a color copy of the informed consent brochure described in section 1.5 of this chapter by printing the informed consent brochure from the state department's Internet web site and including the following information on the back cover of the brochure:</p> <p>(A) The name of the physician performing the abortion and the physician's medical license number.</p> <p>(B) An emergency telephone number where the physician or the physician's designee may be contacted twenty-four (24) hours a day, seven (7) days a week.</p> <p>(C) A statement that follow-up care by the physician or the physician's designee who is licensed under IC 25-22.5 is available on an appropriate and timely basis when clinically necessary.</p> <p>(b) Before an abortion is performed, the provider shall perform, and the pregnant woman shall view, the fetal ultrasound imaging and hear the auscultation of the fetal heart tone if the fetal heart tone is audible unless the pregnant woman certifies in writing, on a form developed by the state department, before the abortion is performed, that the pregnant woman:</p> <p>(1) does not want to view the fetal ultrasound imaging; and</p> <p>(2) does not want to listen to the auscultation of the fetal heart tone if the fetal heart tone is audible.</p> <p>2. On 6/3/15 at 4:45 PM, the medical director and clinic physician #50 was requested to provide</p>	T 024		

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
NAME OF PROVIDER OR SUPPLIER WOMEN'S PAVILION		STREET ADDRESS, CITY, STATE, ZIP CODE 2010 IRONWOOD CIR SOUTH BEND, IN 46635		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 024	Continued From page 7 a copy of a policy/procedure for medical abortion services provided at the clinic and none was provided prior to exit. 3. Review of the following medical records (MR) indicated: a. Patient 21 received medical abortion services on 05/01/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion. b. Patient 22 received medical abortion services on 04/29/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion. c. Patient 23 received medical abortion services on 05/13/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion. d. Patient 24 received medical abortion services on 05/29/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion. e. Patient 25 received medical abortion services on 05/26/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion. f. Patient 26 received medical abortion services on 04/21/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion. g. Patient 27 received medical abortion services on 05/01/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours	T 024		

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
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T 024	<p>Continued From page 8</p> <p>before the abortion.</p> <p>h. Patient 28 received medical abortion services on 05/15/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.</p> <p>i. Patient 29 received medical abortion services on 05/27/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.</p> <p>j. Patient 30 received medical abortion services on 05/27/15 and lacked documentation demonstrating that the requirements of IC 16-34-2-1.1 were completed at least 18 hours before the abortion.</p> <p>4. At 3:55 PM, 4:05 PM and 4:45 PM, during the interview with the facility physician, #50, physician #50 reported:</p> <p>a. The facility has no log of patients with appointment dates, for either the first visit where lab work and consultation/counseling is done, or for their surgical procedures.</p> <p>b. There is a log book kept for documenting surgical patient procedures on the day of surgery, but no log is kept for medical abortion patients.</p> <p>c. The process for medical abortions includes: At the first appointment, an ultrasound is performed and labs (i.e. pregnancy test, Rh testing, hemoglobin and hematocrit) are done. Also, the "state information" and counseling are done and the patient signs their "releases". Then, the Mifiprex (RU486) is given to the patient and 4 tablets of Misoprostol are sent home with the patient to use vaginally at their convenience at about 48 hours later.</p> <p>d. There is no written policy/procedure related to the medical abortion process at the facility.</p>	T 024		

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
NAME OF PROVIDER OR SUPPLIER WOMEN'S PAVILION		STREET ADDRESS, CITY, STATE, ZIP CODE 2010 IRONWOOD CIR SOUTH BEND, IN 46635		
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T 128	Continued From page 9	T 128		
T 128	<p>410 IAC 26-7-1 MEDICAL RECORDS</p> <p>410 IAC 26-7-1(c)</p> <p>(c) A written or electronic register must be kept of all patients treated that provides the following:</p> <ul style="list-style-type: none"> (1) Identification data. (2) Treatment rendered. (3) Attending physician. (4) Condition on discharge. (5) Transfers to hospital facility. (6) Other data deemed necessary by the clinic. <p>This RULE is not met as evidenced by: Based upon document review and interview, the clinic failed to maintain a patient register of all patients receiving services including medical abortion services at the facility for one facility.</p> <p>Findings:</p> <p>1. On 6/3/15 at 3:55 PM, the medical director and clinic physician #50 was requested to provide a patient register indicating all patients obtaining medical abortion services at the clinic and none was provided prior to exit.</p> <p>2. During an interview on 6/3/15 at 3:55 PM, the medical director and clinic physician #50 confirmed the clinic does not maintain a log of patients with appointment dates, for either the first visit where lab work and consultation/counseling is done, or for their surgical procedures, or any other follow up appointments. Physician #50 confirmed that a</p>	T 128		

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011127	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/03/2015
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NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

WOMEN'S PAVILION

2010 IRONWOOD CIR
SOUTH BEND, IN 46635

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
T 128	Continued From page 10 register is kept for documenting surgical patient procedures on the day of surgery and confirmed that no register indicating the treatment rendered for patients obtaining medical abortion services was maintained by the clinic.	T 128		

SHAWN F. SULLIVAN
ATTORNEY AT LAW, LTD

1717 East Wayne Street
South Bend, Indiana 46615

Admitted in Indiana, Illinois, and North Carolina

Direct Line: (574) 233-7860

EXHIBIT 4.a
Legal Opinion to ISDH

URGENT Via Email and Priority Mail

March 3, 2016

Greg Zoeller
Indiana State Attorney General
Indiana Government Center
South 302 W. Washington St, 5th Floor
Indianapolis, IN 46204

Re: *Disposition of the 17 Pending TLC Advocate Complaints, dating back to December of 2014, Reporting 54 potential Criminal Violations;*

- + New evidence – witness statements by the mothers mistreated by Dr. Klopfer and or denied informed consent, starting with the first informed consent complaint filed with the Attorney General in 2014;**
- + The audio and testimonial evidence showing Dr. Klopfer's intent to operate a criminal enterprise (the same evidence that led to 6/3/15 ISDH survey and finding of 10 (out of 10) counts of informed consent violations, I.C. § 16-34-2-1.1, which are now incorporated in the AG's complaint in *In re License of George G. Ulrich Klopfer, D.O., License No. 02000628A*, Medical Licensing Board, Cause No. 2014 MLB 0044; and**
- + Previously supplied witness statements by third party witnesses testifying to Dr. Klopfer's un-professional conduct in the community.**

Dear Mr. Zoeller,

We write requesting a meeting with your office, to occur in the near future, to discuss the mounting criminal activity associated with Dr. Klopfer's operation of the Women's Pavilion. We hope to immediately meet concerning the pending unresolved 17 complaints filed with your office by the TLC Advocates (dating back to December 2014), new evidence related to them (an example witness statement attached), as well as the audio and testimonial evidence of Dr. Klopfer's clinic being set up to perpetually violate the informed consent law (I.C. § 16-34-2-1.1(a)(1)) by Dr. Klopfer, and the witness statement pertaining to Dr. Klopfer's unprofessional conduct in the community. I am eager to advise my anxious clients that our Attorney General is as serious about these violations of the Criminal Code as we are and that we have scheduled a meeting to discuss them. We have pleaded with them to be patient with the Attorney General's office, and have distinguished your office with Indiana State Department of Health ("ISDH"), but they are on edge given the speed at which the wheels of justice are turning in regards to Dr. Klopfer.¹

¹ Our clients are an ever expanding group. We represent the The Life Center, TLC Advocates, the 860 petitioners who signed the Answer the C.A.L.L. (Citizens Against Licensing the Lawless) Campaign, and the new class of clients consisting of the mothers who were denied the informed consent prior to receiving an abortion. These mothers desired the 18 hours to consider the information required by the state, but they did not receive the information, and they were not accorded 18 hours to consider the information. As an example of this growing constituency, we are attaching the witness statement of the mother associated with the first complaint filed with your office. We hope to open up this confidential litigation file to the AG's

I will not try to provide an exhaustive list of the issues that could potentially be discussed at the meeting we are requesting. It is sufficient to say that my clients are concerned by the recent actions of the ISDH, which refused to investigate 15 of their 17 complaints (the same complaints we submitted to the AG's office) thereby limiting their prosecution of 18-hour rule violations to 10 infractions in May of 2015, and ignoring the 51 violations documented by the TLC advocates in November and December of 2015 and from June to November 2015. My clients are particularly disturbed by ISDH's ignoring of complaints of 18-hour infractions committed immediately following the settlement agreement, i.e., on November 3, 4 and 6, 2015.

The meeting we are requesting will be invaluable to the AG. Obviously our lawyers and our clients can provide information as well as testimonial and documentary information if you would find it useful at your trial in the M.L.B. proceeding, *In re Klopfer*. Equally important, our clients have leads and information that is pertinent to your adverse or cross examination. And of course the meeting we are requesting is necessary for resolving the 17 pending complaints of criminal violations by Dr. Klopfer:

- ◆ Ellen Master, AG File 14-CP-63223 (12/2/14) (reported 2 separate and distinct informed consent violations and for one of them there is new evidence, a witness statement);
- ◆ Dr. Jennifer Borek, AG File 15-CP-**** (2/9/15) (reported testimony of Dr. Klopfer's intentional practice of violating informed consent laws with all medical abortions);
- ◆ Alyson Cox, AG File 15-CP-53691 (4/1/15) (obtained audio evidence of Dr. Klopfer's intentional practice of violating informed consent laws with all medical abortions);
- ◆ Pamela Washburn, AG File 15-CP-**** (7/3/15) (reported 1 distinct informed consent violation);
- ◆ Mary Ball, AG File 15-CP-**** (7/6/15) (reported 1 distinct informed consent violation);
- ◆ Amber Dolby, AG File 15-CP-**** (7/28/15) (reported 2 distinct informed consent violations);
- ◆ Ellen Master, AG File 15-CP-58727 (8/26/15) (reported 9 distinct informed consent violations);
- ◆ Shawn Master, AG File 15-CP-**** (8/26/15) (reported 10 distinct informed consent violations);
- ◆ Pamela Washburn, AG File 15-CP-52011 (11/20/15) (reported 1 abortion without a license);
- ◆ Dr. Jennifer Borek, AG File 15-CP-58184 (11/24/15) (reported 4 distinct informed consent violations);
- ◆ Nick Keszei, AG File 15-CP-**** (11/24/15) (reported 3 distinct informed consent violations);
- ◆ Zach Spaulding, AG File 15-CP-61488 (11/24/15) (reported 3 distinct informed consent violations);
- ◆ Jenna Kovatch, AG File 15-CP-****(11/27/15) (reported 5 distinct informed consent violations);
- ◆ Dr. Jennifer Borek, AG File 15-CP-****(11/27/15) (reported 6 distinct informed consent violations occurring after appeal of license revocation dismissed);
- ◆ Jenna Dyer, AG File 15-CP-**** (11/27/15) (reported the same 6 informed consent violations occurring after appeal of license revocation dismissed);
- ◆ Pamela Washburn, AG File 16-CP-51978 (2/10/16) (reported activity, possibly an abortion, without a license).

In closing, if there is any type of stipulation or confidentiality agreement that would facilitate the meeting requested herein, we would gladly oblige. Thank you in advance for your consideration to this request and do not hesitate to call me to discuss this matter.

Sincerely,

A handwritten signature in black ink that reads "Shawn F. Sullivan". The signature is stylized with a large, sweeping "S" and a cursive "F".

Shawn F. Sullivan, IN Bar No. 21472-71
Attorney for TLC Advocates, The Life Center, and those similarly situated
S. F. SULLIVAN, ATTORNEY AT LAW, LTD.,

Ex. 1: Mandy Witness Statement

c: Mike Pence
Office of the Governor
State House
Room 206
Indianapolis, IN 46204-2797

Darren Covington/ Kirk E. Masten
Director, Medical Licensing Board
Indiana Government Center
402 W. Washington St., Room W072
Indianapolis, IN 46204

Lindsey Craig
Family Policy Director
Governor's Office, Room 206
Indianapolis, IN 46204-2797

SHAWN F. SULLIVAN
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1717 EAST WAYNE STREET
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Admitted in Indiana, Illinois, and North Carolina

Via email <rsnyder1@isdh.in.gov>

January 29, 2016

Randall Snyder, Director of Acute Care Division
Indiana State Department of Health (ISDH)
2 North Meridian Street, 4A
Indianapolis, IN 46204

Re: Application for Abortion Clinic License by Women's Pavilion and/or MGK Inc. (Dr. Ulrich "George" Klopfer), 2010 Ironwood Circle, South Bend, IN 46635

Dear Mr. Snyder,

I write on behalf of the TLC Advocates (who have submitted complaints containing 51 informed consent violations), the members and supporters of The Life Center, and the over 900 concerned citizens who have signed the "Answer the C.A.L.L. (Citizens Against Licensing the Lawless)" petition, all of whom are deeply concerned about Dr. Klopfer's abortion clinic re-licensure application, which could be filed as early as February 2, 2016. The lack of administrative enforcement here, with only an 88-day stay of operations,¹ when the clinic admitted 10 informed consent violations (during your June 3, 2015 Survey), as well as indisputable evidence that Dr. Klopfer systemically violated the informed consent law, is extremely troubling. But more troubling is the refusal of the ISDH to process our complaints filed after the June 3, 2015 Survey because – according to ISDH – they were "repetitive." This excuse for inaction was matched by the startling claim by the ISDH that they do not have jurisdiction to prosecute the TLC Advocates' reporting of 11 illegal abortions (with each one of the illegal abortions being conducted without informed consent) between November 3 and November 6, 2015.

The harm to women is mounting. The attached statement, as an example, is from the very first informed consent violation reported to the ISDH. While I will only release details regarding these statements over the phone, due to privilege concerns, please know that we continue to gather this type of evidence to demonstrate the damage caused by ISDH's lackadaisical enforcement policies. Sadly, although the laws are set up to protect women from this type of damage, the laws are not being enforced. In this case, despite Dr. Klopfer's intentional and systemic violation of the criminal laws, and despite the complaints of TLC Advocates that have documented 51 illegal abortions along with testimonial evidence and an audio-recording the Women's Pavilion's commitment to intentionally denying informed consent, ISDH ignores the magnitude of the situation to the detriment of Dr. Klopfer's patients. Moreover, in the opinion of our clients, and the legal opinion of our outside counsel, the 11 illegal abortions that we reported as occurring after Dr.

¹ Dr. Klopfer signed the settlement documents on November 2, 2015, and the ISDH immediately began giving him credit for his 90-day suspension from operations even though he was still operating. This is just one more anomaly in a history of lackadaisical enforcement of the law in regards to the Women's Pavilion and Dr. Klopfer.

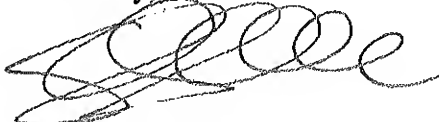
Klopfers had settled with ISDH, but during the extra days of operation that ISDH granted to Women's Pavilion (November 4th through 6th, 2015), are the most poignant violations that should have been investigated by ISDH because those are felonies and represent the doctor's unrepentant, incorrigible, criminal mindset, which should preclude any doctor's ability to apply for a clinic license.²

In the case of Dr. Klopfer and Women's Pavilion, however, there are many more reasons that would prompt the reasonable regulatory official to bar Dr. Klopfer from ever obtaining an abortion clinic license again. For starters, his rap sheet of violations with ISDH and prosecutors should have been the basis for extensive fines, especially with his admissions of systemically violating what is a criminal law. How else does the ISDH plan to deter him and deter other abortionists from setting up business plans that systemically violate the law? When the facts of this case become known to all of the populace, this will be a very embarrassing moment for Indiana. And add to that the growing body of injured parties because the ISDH chooses to license the lawless.

I could go on about the awkward nature of the current situation where the ISDH is essentially protecting the abortionist, but already, according to your lead attorney in this matter, Matthew Foster, you consider me to have disdain for the ISDH. I do not harbor disdain for the ISDH. Such a defensive remark to explain my zealous advocacy is churlish and turns the entire matter on its head. It is I, on behalf of thousands of others, that seek to *represent the purpose and rules of ISDH*. Far from disdaining the ISDH, I think the ISDH and its Acute Care Division are essential to protecting the public from lawless abortionists. I think the ISDH holds the premiere responsibility in protecting mothers and enforcing the laws on the books. Unfortunately, though, the current administration of the ISDH are hell-bent on undermining ISDH's own rules. It is the current administration of ISDH and its legal staff that are hell-bent on making a mockery of the abortion laws by refusing to investigate credible complaints and by fostering positions that are more damaging than incompetent. I am seeking, and my clients are pleading – and have been pleading since they launched the Answer the C.A.L.L. campaign last February – that the ISDH simply cease the shenanigans that allow this repeat offender to continue to plague Indiana women and the rule of law.

Please remedy this situation immediately before we have a disaster on our hands in Indiana.

Sincerely,

A handwritten signature in black ink, appearing to read 'Shawn F. Sullivan', with a stylized, cursive script.

Shawn F. Sullivan

² By November 2, 2015, when Dr. Klopfer executed the settlement documents, he was already facing Medical Licensing Board allegations that he violated the informed consent law, he had already admitted the 10 informed consent violations found by the ISDH, and he was facing revocation of his license for informed consent violations. That he would immediately violate the informed consent laws that last week of operation, in full view of the TOLC Advocates, while the ink was still drying on the settlement document, in full view of the TLC Advocates, demonstrates that he believes he is beyond authentic prosecution by the ISDH. That ISDH would not investigate these, even when knowing that Dr. Klopfer admitted during the June 3, 2015 survey that violating the informed consent law was his *modus operandi*, proves that ISDH is only feigning regulation of Women's Pavilion and Dr. Klopfer.

I, Mandy [REDACTED] :

1. On November 28, 2014, I went to the Women's Pavilion for my counseling appointment.
2. I was there for counseling regarding an abortion, but on my way into the Women's Pavilion, I talked to a woman on the sidewalk by the name of Ellen Master. She presented alternatives to abortion, such as adoption, and offered me financial, legal, and medical assistance to eliminate the pressure on me to have an abortion.
3. I went inside to my counseling appointment, considering what Mrs. Master had told me. But during the counseling visit the abortionist asked me to sign-off on some paperwork and gave me a pill.
4. Upon my exit from the Women's Pavilion, I talked again to Mrs. Master, and, although I wanted to consider these options, I informed Mrs. Master that it was too late because the abortionist had already given me the abortion pill that I took in his office.
5. This all occurred over a two hour period during my first visit to the abortionist on November 28, 2014.

Mandy [REDACTED]
Mandy [REDACTED]

12/1/15 Date



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

EXHIBIT 4.c
Legal Opinion to ISDH

July 20, 2015

Mr. Shawn Sullivan
1717 East Wayne Street
South Bend, Indiana 46615

Dear Mr. Sullivan:

The ISDH is in receipt of your letter received on July 17, 2015. Your letter, on behalf of your clients, TLC Advocates, voiced concerns over the ISDH's handling of the regulation of abortion clinics in this state. Specifically, you are dissatisfied over the closure of the TLC Advocate Complaints of Pam Washburn and Mary Ball. As you stated, these complaints relate to violations of Ind. Code § 16-34-2-1.1 concerning timing of the informed consent.

Ms. Pam Washburn and Mary Ball's complaint concerned the same violation identified and investigated by the ISDH on June 3, 2015 with its complaint survey of Women's Pavilion. The division has acted upon the results of the substantiated complaint and an action is pending before an Administrative Law Judge for the ISDH. An additional survey of the same complaint/allegation will not be conducted by the ISDH.

Thank you for your patience as the administrative process runs its course through the required channels.

Respectfully,

Randall Snyder, PT, MBA
Division Director, Acute Care



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www.statehealth.in.gov

To promote and provide
essential public health services.



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

EXHIBIT 4.d
Legal Opinion to ISDH

November 30, 2015

Via Regular Mail & Email (tomborekmc@gmail.com)

Mr. Tom Borek, Legal Assistant
Shawn F. Sullivan, Attorney at Law, LTD
1717 East Wayne Street
South Bend, IN 46615

Re: Complaints Regarding Women's Pavilion

Dear Mr. Borek:

The Indiana State Department of Health ("ISDH") has received your emails of November 23, 2015 and November 30, 2015, which delivered complaints made by several persons about activity at Women's Pavilion in South Bend. Specifically, we received complaints from Nick Keszei, Jennifer Borek, Ellen Master, and Zachary Spaulding on November 23, and from Pamela Washburn, Jennifer Borek, Jenna Kovatch, and Kristine Hunsley on November 30.

ISDH does not presently regulate Women's Pavilion, which is no longer licensed as an abortion clinic. As a courtesy, however, we have forwarded the complaints to the Office of the Indiana Attorney General, which will respond as it deems appropriate. Thank you,

Very truly yours,

Matthew Foster, Litigation Chief
ISDH Office of Legal Affairs

MWF/gb



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

INDIANA STATE DEPARTMENT OF HEALTH ("ISDH") AND OTHER ENFORCEMENT BODIES IN INDIANA ARE PROTECTING AN ABORTION DOCTOR WHO REPEATEDLY AND INTENTIONALLY VIOLATES THE LAW AND ENDANGERS WOMEN

DEMAND that ISDH and other Indiana agencies and law enforcement ABIDE by the LAW and PROTECT WOMEN!!

Challenge Indiana Law Enforcement to PROTECT HOOSIERS:

1. ISDH failed to fine the out-of-state abortionist, Dr. Klopfer, even though Dr. Klopfer admitted to operating his abortion clinic in violation of the criminal laws requiring him to provide mothers with informed consent.
2. ISDH dismissed the informed consent violations and all other violations against Dr. Klopfer without permanent revocation of his clinic license. In fact, Dr. Klopfer still has his medical license and can obtain a clinic license.
3. ISDH has ignored and still refuses to investigate over 48 complaints filed by The Life Center ("TLC"). These complaints show more informed consent violations by Dr. Klopfer and other illegal abortions.

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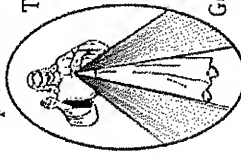
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EXHIBIT 5.a
Legal Opinion to ISDH

The Life Center

The Life Center ("TLC"), located adjacent to Dr. Klopfer's abortion clinic, does not only serve to report on Dr. Klopfer's violations. TLC actually serves as the reason why a mother's informed consent, as required by Indiana law, is so vital to enabling a mother to make the best choice for her and her family. In order to enable a mother to make an informed choice about abortion -- instead of feeling forced to have an abortion -- TLC sidewalk counselors offer adoption as well as medical, financial, and legal support, protection from those forcing abortion, and shelter from domestic violence. In just three years, 102 mothers hearing this offer by TLC have decided not to go through with their scheduled abortion. That is why Dr. Klopfer and other pro-abortion forces are willing to do anything, including violating the informed consent law, to prevent mothers from considering these and other options. We know mothers want to hear what TLC has to say before going through with an abortion because they have said so. And regretfully, those mothers who were denied informed consent by Dr. Klopfer are lamenting their uninformed choice.



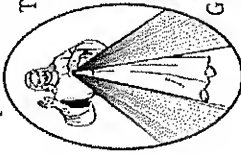
TLC is sponsored and operated by
APOSTOLATE of DIVINE MERCY
— in service of HUMAN LIFE

Making visible the Divine Mercy of Jesus
— through public witness, worship, service and education

Go to www.DivineMercyforLife.net

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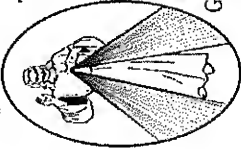
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OCTOBER 27, 2017 (/ABBYJOHNSON/2017/9/6/WHOLE-WOMENS-HEALTH-EXPOSED)

Whole Woman's Health Exposed (/abbyjohnson/2017/9/6/whole- womens-health-exposed)

Detailed inspection reports obtained by And Then There Were None, a group started by former Planned Parenthood director Abby Johnson that helps abortion workers leave their jobs, reveals dozens of health violations levied against Whole Woman's Health, which currently operates 4 abortion facilities in Texas.

Whole Woman's Health is a chain of abortion facilities located mostly in Texas, with clinics also in Maryland, Minnesota and Illinois, who was also the plaintiff in the 2016 Supreme Court case *Whole Woman's Health v. Hellerstadt*. They won their case, which threw out laws in Texas which would have required abortion facilities to meet common health and safety standards and for abortionists to have admitting privileges to a hospital within 30 miles of the facility.

"As is common in the abortion industry, making a hefty profit is the bottom line and must be achieved over anything else, including the health and safety of patients," said Abby Johnson. "The reports we obtained show a blatant disregard for women's health and safety, as well as the safety of the abortion workers themselves, on the part of Whole Woman's Health. Women deserve this information.

Before the Supreme Court decided in *Whole Woman's Health* favor, the abortion facility in Austin had shut down and was put up for sale. Abby Johnson toured that facility as a prospective buyer, snapping photos of what appears to be blood on the walls and dirty equipment.

"I was appalled at the state of the Austin Whole Woman's Health," said Ms. Johnson. "It looked more like a prison than an actual facility where patients went for healthcare. Disgusting does not do it justice."

According to the inspection reports, these are some examples of health violations at various Whole Woman's Health facilities from 2011-2017:

- Failed to properly disinfect and sterilize instruments that were used from woman to woman

- Failed to provide a safe and sanitary environment – products of conception were being examined and contaminated instruments were being washed in the same room
- Emergency cart contained expired supplies and medications
- Cracks, rips and tears on the vinyl covers of exam tables
- There was a hole in the cabinet flooring that had “the likelihood to allow rodents to enter the facility”
- Suction machines had numerous rusty spots having the “likelihood to cause infection”

“No wonder Whole Woman’s Health took their case all the way to the Supreme Court. They needed to win in order to keep their doors open and make money. They had everything to lose if they didn’t win,” said Ms. Johnson.

To speak to Abby Johnson at And Then There Were None, please contact Kristina Hernandez at 908-902-8473.

PRINTED: 08/03/2017
FORM APPROVED

Texas Department of State Health Services			
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140013	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 07/24/2017
NAME OF PROVIDER OR SUPPLIER		STREET ADDRESS, CITY, STATE, ZIP CODE	

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 000	<p>TAC 139 Initial Comments</p> <p>Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p> <p>An entrance conference was held with the Clinic Nurse Manager the morning of 7-24-17. The purpose and process of the initial licensure survey were discussed, and an opportunity given for questions.</p> <p>Initial licensure is recommended, with an approved plan of correction.</p> <p>An exit conference was held with the Clinic Nurse Manager and the Director of Clinical Services on the afternoon of 7-24-17. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p>	A 000		
A 126	<p>TAC 139.41(a) Policy Development and Review</p> <p>(a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and nonprofessionally</p>	A 126		

<p>1. IDENTIFY THE DEFICIENCY WITH PRECISION</p> <p>acceptable environment. These written policies shall include at a minimum the following:</p>			
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SOD - State Form	TITLE	(X6) DATE
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE		

STATE FORM	8892	H7XF11	If continuation sheet 1 of 8
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Texas Department of State Health Services				
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140013	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 07/24/2017
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE		STREET ADDRESS, CITY, STATE, ZIP CODE 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753		
(X4) ID PREFIX TAG A 126	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG A 126	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 1			
	This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are			

administered so as to provide health care in a safe and professionally acceptable environment.

Findings were:

During a tour of the facility on 7-24-17, a random count of Fentanyl (a Schedule II narcotic medication) was performed. 150 ml of Fentanyl was present in boxed vials. 2 ml of Fentanyl was present in an unopened vial (not in a box). 2 syringes, each pre-filled with 0.5 ml of the drug, represented 1 ml of Fentanyl, for a total of 153 ml of Fentanyl. The Fentanyl count on 7-24-17 was verified by staff #7, present during the tour and the narcotic count. The narcotic count sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #6 and staff #9). In an interview with staff members #6 & #7, neither member was able to explain the 1 ml Fentanyl discrepancy and both staff stated that no patients had been seen since 7-21-17.

According to <https://www.deadiversion.usdoj.gov/schedules/>, a Schedule II drug is described as follows:
"Schedule II/III Controlled Substances (2/2N)

Substances in this schedule have a high potential for abuse which may lead to severe psychological

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140013	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 07/24/2017
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A 126	Continued From page 2 or physical dependence. Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone. Examples of Schedule I/II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital." Facility policy titled "Medication Therapy Practices" stated, in part: "Controlled Medications Closing Count" 1. Each day that Controlled Medications are administered, at the end of the day, two staff will open the safe and count each drug on the Controlled Medication log. ...	A 126			

<p>8. Any discrepancies between the actual closing count and the anticipated closing count should be resolved and reported to the clinical manager. Discrepancies that cannot be resolved should generate a Narcotics Deviation Report. Deviation reports of concern, i.e. that indicate missing drugs or careless handling, should be shared with the Medical Director/Consultant and included in the Quarterly Review."</p> <p>The above was confirmed in an interview with staff #6 and staff #7 on the afternoon of 7-24-17.</p>		
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SOD - State Form
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If continuation sheet 3 of 8

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Texas Department of State Health Services

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE		STREET ADDRESS, CITY, STATE, ZIP CODE 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE

A 257	Continued From page 3	A 257		
A 257	<p>TAC 139.49(d)(5)(L)(ii)(I - V) Infection Control Standards</p> <p>(L) Performance records.</p> <p>(ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include:</p> <p>(i) the sterilizer identification;</p> <p>(II) sterilization date and time;</p> <p>(III) load number;</p> <p>(IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts);</p> <p>(V) identification of operator(s);</p> <p>This Requirement is not met as evidenced by:</p> <p>Based on a review of performance records and interview, the facility failed to ensure that each sterilizer was monitored during operation for pressure, temperature, and time at desired temperature and pressure, as evidenced by the fact that a record was not maintained that included: duration and temperature of exposure phase (if not provided on sterilizer recording charts).</p> <p>Finding included:</p> <p>Review of the autoclave logs for May, June, and July 2017 revealed that pressure, temperature, and duration of exposure at desired temperature and pressure of the sterilized logs was not documented.</p> <p>In an interview on 07/24/17, staff member #7 stated that the new autoclave forms have an area to document the pressure and temperature,</p>	A 257		

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140013	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 07/24/2017
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE		STREET ADDRESS, CITY, STATE, ZIP CODE 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753		
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A 257	Continued From page 4 however the facility was utilizing old logs that did not contain a prompt to document this information. The new forms also did not have an area to document duration of the exposure phase. With no documentation of these elements it is unknown if these loads and instruments were effectively sterilized. Facility policy titled "Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" states, in part: "Performance Records Performance records for all sterilizers will be	A 257		

maintained for each cycle. And will be retained for two years.(sic) These records will be available for review within two hours during the specified two-year period.

All sterilizers will be monitored during operation for pressure, temperature, and time at desired temperature and pressure. The performance record will include:

- Sterilizer identification number
- Sterilization date
- Sterilization time
- Load number
- Pack ID#
- Duration and temperature of exposed phase
- Identification of operator
- Results of biological tests and dates performed
- Time/temperature recording charts from each sterilizer"

The above findings we confirmed on 07/24/17 in an interview with staff member #7.

SOD - State Form
STATE FORM

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If continuation sheet 5 of 8

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA
IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION
A. B. C. D. E. F. G. H. I. J. K. L. M. N. O. P. Q. R. S. T. U. V. W. X. Y. Z.

(X3) DATE SURVEY
COMPLETED

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE		STREET ADDRESS, CITY, STATE, ZIP CODE 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753		A. BUILDING: _____ B. WING: _____		07/24/2017	
140013							
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETE DATE		
A 315	Continued From page 5	A 315					
A 315	House Bill 2 Medical and Clinical Services A physician must provide the pregnant woman with: a) a telephone number by which the pregnant woman may reach the physician, 24 hours a day to request assistance for any complications that arise from the abortion or ask health-related questions regarding the abortion; and b) the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.	A 315					
	This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the physician failed to provide the pregnant women with the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.						
	Findings were: During a review of 21 clinical records, 10 of the 21 records (patients #2, #3, #4, #5, #6, #12, #13, #14, #15 and #16) contained no documentation that the patient had been furnished with the name and/or telephone number of the nearest hospital to the home of the pregnant woman at which an						

<p>to the name of the pregnant woman at which an emergency arising from the abortion would be treated.</p> <p>-Patients #2, #3, #4, #5 and #6 had been provided with a hospital name but no telephone number for the hospital.</p> <p>-Patients #12, #13, #14, #15 and #16 had been</p>			
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SOD - State Form
STATE FORM

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If continuation sheet 6 of 8

PRINTED: 08/03/2017
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Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140013	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 07/24/2017
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE		STREET ADDRESS, CITY, STATE, ZIP CODE 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753		
(X4) ID PREFIX TAG A 315	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG A 315	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	Continued From page 6 provided with neither a hospital name nor a telephone number for the hospital. The above was confirmed in an interview with			

staff #7 on the afternoon of 7-24-17.

A 327

House Bill 2 Medical and Clinical Services

Physicians must ensure that abortion-inducing drugs are used according to FDA regulations that require the women to visit the physician in person for each of the two doses of the abortion pill, as well as for a follow-up appointment within 14 days. The physician must provide the woman with a copy of the final printed label of the abortion-inducing drug.

This Requirement is not met as evidenced by:
Based on a review of clinical records and an interview with staff, the physician failed to ensure that the patient was scheduled for a follow-up appointment within 14 days.

Findings were:

Based on the review of 21 clinical records, 1 of 21 (patient #1) was not scheduled to return to the clinic for a follow-up visit within the required 14

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If continuation sheet 7 of 8

Texas Department of State Health Services		STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140013	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 07/24/2017
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE			STREET ADDRESS, CITY, STATE, ZIP CODE 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE		
A 327	Continued From page 7 days (appointment was scheduled for 21 days after). The above was confirmed in an interview with staff #7 on the afternoon of 7-24-17.	A 327				

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SOD - State Form
STATE FORM

5899

H7XF11

If continuation sheet 8 of 8

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Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED: 11/08/2016
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NAME OF PROVIDER OR SUPPLIER		STREET ADDRESS, CITY, STATE, ZIP CODE	
WHOLE WOMAN'S HEALTH OF SAN ANTONIO		4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)
A 000	<p>TAC 139 Initial Comments:</p> <p>Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p> <p>An entrance conference was held with the facility co-owner on the morning of 11-7-16. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.</p> <p>Continued licensure is recommended, with an approved plan of correction.</p> <p>An exit conference was held with the facility co-owner and other administrative staff on the afternoon of 11-8-16. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p>	A 000	<p>REVIEWED</p> <p>DEC 13 2016</p> <p>By: Paula Wilson, LSC</p>
A 033		A 033	

TITLE

(X6) DATE

Director of Criminal Services 12/13/2016
 WVQF11
 If continuation sheet 1 of 5

STATE FORM

PRINTED: 11/21/2016
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Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING:		(X3) DATE SURVEY COMPLETED 11/08/2016
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO			STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD 5 SUITE 30 SAN ANTONIO, TX 78222		
(X4) ID PREFIX TAG A 143	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG A 143	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETE DATE
A 143	Continued From page 2	A 143			
A 143	TAC 139.43(2)(3)(4)(5) Personnel Policies (2) a requirement for orientation of all employees, volunteers, students and contractors to the policies and objectives of the facility and participation by all personnel in employee training specific to their job. (3) job-related training for each position.	A 143	A 143 The Clinic Manager will be responsible for ensuring staff members received an annual evaluation of employee's performance. The Clinic Manager has created a detailed schedule to complete all staff's annual		

(4) a requirement for an annual evaluation of employee performance;
(5) in-service and continuing education requirements;

This Requirement is not met as evidenced by Based on review of documentation and interview, the facility failed to ensure that an annual evaluation of employee performance was completed.

Findings included:

Review of the facility personnel files revealed that 6 out 10 employees did not have a current annual evaluation completed.

- * Staff member # 1's last annual evaluation was completed on 10/15/15.
- * Staff member # 5's last annual evaluation was completed on 07/14/14.
- * Staff member # 7 had no annual evaluation completed with a hire date of 08/17/15.
- * Staff member # 8's last annual evaluation was completed in March 2015.
- * Staff member # 9 last had a 90 day review completed on 04/10/14.
- * Staff member # 10's last annual evaluation

evaluations, this process was started on November 15, 2016, and all evaluation reports will be submitted to the DCS by January 15, 2017.

The Director of Clinical Services will ensure that new Clinic Manager is trained to adhere to the current written employee policy.

In order to ensure continued compliance with the Employee Policies, the Clinic Manager will ensure that all staff files are reviewed and evaluations are scheduled as part of the QA committee meeting.

01/15/2017

PRINTED: 11/21/2016
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Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 149007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 11/08/2016
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF SAN ANTONIO			STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E. SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
A 143	Continued From page 3 was completed on 07/17/15. In an interview on 11/08/16, staff members # 10 and 11 confirmed the facility was unable to locate current annual evaluations for the above staff members.	A 143			
A 197	TAC 139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows: (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained, to protect the health and safety of patients and staff at all times. This Requirement is not met as evidenced by:	A 197			
A 201	TAC 139.48(1)(E)(F) Physical & Environmental	A 201			

requirements.			
<p>The physical and environmental requirements for a licensed abortion facility are as follows.</p> <p>(1) A facility shall:</p> <p>(E) store hazardous cleaning solutions and compounds in a secure manner and label substances;</p> <p>(F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of §§229.161 - 229.171 of this title (relating to Texas Food</p>	WVQF11	If continuation sheet, 4 of 6	
<p>SOP - State Form</p> <p>STATE FORM</p>			

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Texas Department of State Health Services			
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED: 11/08/2016
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD. BLDG 5 SUITE 30 SAN ANTONIO, TX 78222	

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION: (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 201	<p>Continued From page 4</p> <p>Establishments):</p> <p>This Requirement is not met as evidenced by: Based on observation, the facility failed to store hazardous-cleaning solutions and compounds in a secure manner.</p> <p>Findings were:</p> <p>During a tour of the facility on 11-8-16, the laundry area (closed off only by a curtain) contained a shelving unit where various cleaners and chemicals such as germicide, enzymatic cleaner and bleach were stored.</p> <p>The above was confirmed in an interview with the co-owner and Director of Clinical Services on the afternoon of 11-8-16.</p>	A 201	<p>A201</p> <p>The Clinic Manager will be responsible for ensuring that hazardous cleaning solutions and compounds are stored in a secure manner.</p> <p>Cleaners and solutions stored in laundry room area will be moved to a designated storage area. A lock will be installed on the storage closet door.</p> <p>The Clinic Manager will conduct an in-service with all staff to advise what materials will be stored in the closet and also to advise staff that the storage room door must remain locked during clinic hours.</p> <p>To ensure continued compliance, the QA committee will inspect the storage closet during the QA committee meeting.</p>	<p>12/23/2016</p> <p>01/17/2017</p>

PRINTED: 08/29/2016
FORM APPROVED

Texas Department of State Health Services STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(A1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(A2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(A3) DATE SURVEY COMPLETED
		5083536		08/18/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMEN'S HEALTH OF MOBILE, LP		STREET ADDRESS, CITY, STATE, ZIP CODE 902 SOUTH MAIN STREET HOUSTON, TX 77001		
(A4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(A5) COMPLETE DATE
A 001	TAC 139 Initial Comments Note: The State Form is an official legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency chart(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SSA) should be notified immediately. An unannounced visit was made on the morning of 8/13/2016 to conduct a Re-licensure Survey to determine compliance with 25 TAC Chapter 139 State Licensing Rules for Abortion Facility.	A 000	Accepted 8/19/16	

An entrance conference was conducted with the Clinic Manager. The purpose of the visit and procedure for the survey was discussed.

An exit conference was conducted on 8/13/16 with the Clinic Manager. Violations were cited. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for facility to provide evidence of compliance with those requirements for which non-compliance had been found.

A 157 TAC 159.48(1)(A) Physical & Environmental Requirements A 157

The physical and environmental requirements for a licensed abortion facility are as follows.

- (1) A facility shall:
 - (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times.

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LABORATORY

STATE FOR

TITLE

L.M. CLINIC MANAGER

DATE

10/14/2016

If continuation sheet 1 of 2

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 0080036	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 09/13/2016
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
A 197	Continued From page 1	A 197			
	<p>This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to provide a clean and sanitary environment to protect the health and safety of patients and minimize the transmission of infections.</p> <p>The findings included:</p> <p>Observations on 9/15/14 at 10:00 a.m. of the facility's pathology room, revealed the laminate counter top was warped and bowed away from the particle board based, exposing the particle board. The counter top was no longer a wipeable surface which could harbor bacteria and infectious matter. This room was also used to clean and pack surgical instruments.</p> <p>Interview with the facility clinical coordinator confirmed the above finding.</p>		<p>A 197</p> <p>The Clinic Manager will be responsible for ensuring that our facility maintains a safe and sanitary environment, properly constructed and equipped to protect the health and safety of patients and staff at all times.</p> <p>During the survey on 09/13/2016, the surveyor noted that the laminate countertop in the pathology room was warped and bowed away from the particle board exposing the particle board material.</p> <p>The Clinic Manager will hire a contractor to remove and replace damaged countertop in Pathology Room.</p> <p>In order to ensure that the facility maintains a healthy and safe environment for patients and staff, the Clinic Manager will complete a physical walk through of the facilities while</p>		10/30/2016

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If continuation sheet 2 of 2

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	(X5) COMPLETION DATE

Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.

An on-site unannounced survey was conducted on 11/15/2011 to determine the facility's compliance with the requirements of the Abortion Facility Reporting and Licensing Rules. An entrance conference was conducted with the Administrator on 11/15/2011 at 2:00 PM. In the process of the survey was explained and an opportunity was provided for questions and discussion.

An exit conference was held in the waiting area of the clinic on 11/17/2010 at 8:00 AM with the Administrator. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for questions and discussion.

A 12

A 125

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TITLE

DATE

DIRECTOR OF MEDICAL SERVICES

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Continuation sheet 1 of 17

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Texas Department of State Health Services				
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 125	Continued From page 1	A 125	A125	

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If continuation sheet 2 of 17

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 000137		(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703				
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
A 247	<p>138.44(c) Orientation, Training, Competency</p> <p>(c) The facility shall ensure that staff responsible for sterilization of critical surgical instruments are trained by the facility to meet the requirements of §138.46(p) of this title (relating to Infection Control Standards) and demonstrate competency in performing the sterilization procedures at the facility.</p> <p>This Requirement is not met as evidenced by: Based on demonstration and interview the facility failed to ensure the staff was trained in sterilization process of surgical instruments.</p> <p>During the demonstration by staff #2 when using peel pouches (a type of package used for sterile instruments that is sealed with a peel away adhesive seal) revealed staff #2 did not know the proper technique for the use of the peel pouch. When staff #2 sealed the sterile package she left a open area in the package.</p> <p>On touring the sterilization area where sterile instruments are kept, found eight (8) peel pouches sealed and sterilized with open areas still present in the sterile package. Opened a wrapped sterilized instrument and found no sterilization indicator in the package. Staff #2 did not know what a sterilization indicator was or what it is used for in the sterilization process.</p> <p>An interview with staff #2 on 11/18/2011 at 4:00 PM, asked the surveyor to demonstrate the proper technique on how to seal the packages. An interview with the Administrator on 11/16/2011 at 4:30 PM, confirmed there were no standards.</p>		A 247	<p>The Clinic Administrator will be responsible for ensuring all personnel involved in Decontamination and Sterilization Processes will complete the Orientation and Training Checklists, as well as demonstrate accurate competency. (See procedure attached)</p> <p>A staff Re-Training and Re-Orientation of all personnel involved in Infection control practices will be facilitated by 02-10-12. This training will include a thorough review of WWH Sterilization and Decontamination practices, and explanation of the Importance of sterilization indicators in all surgical pack and instruments. All instruments will be re-sterilized following the proper methods of Decontamination and sterilization.</p> <p>The Clinic Administrator will be responsible for ensuring all Decontamination and Sterilization practices are being followed accurately by inspecting all surgical packs and pouches on a weekly basis for a period of 90 days if no deviations are found during this evaluation period. The Director of</p>	02-10-12	

indicators in the facility,	Medical Services will assess competency of the Administrator as well as all staff involved in Infection Control Practices during QA Visits.
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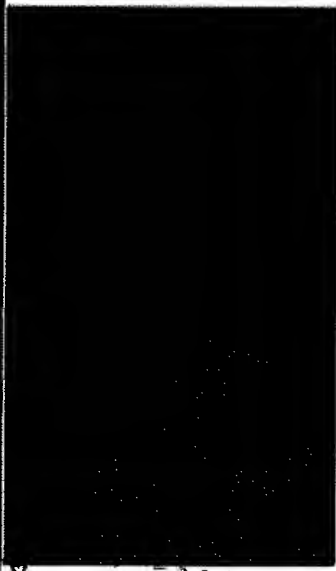
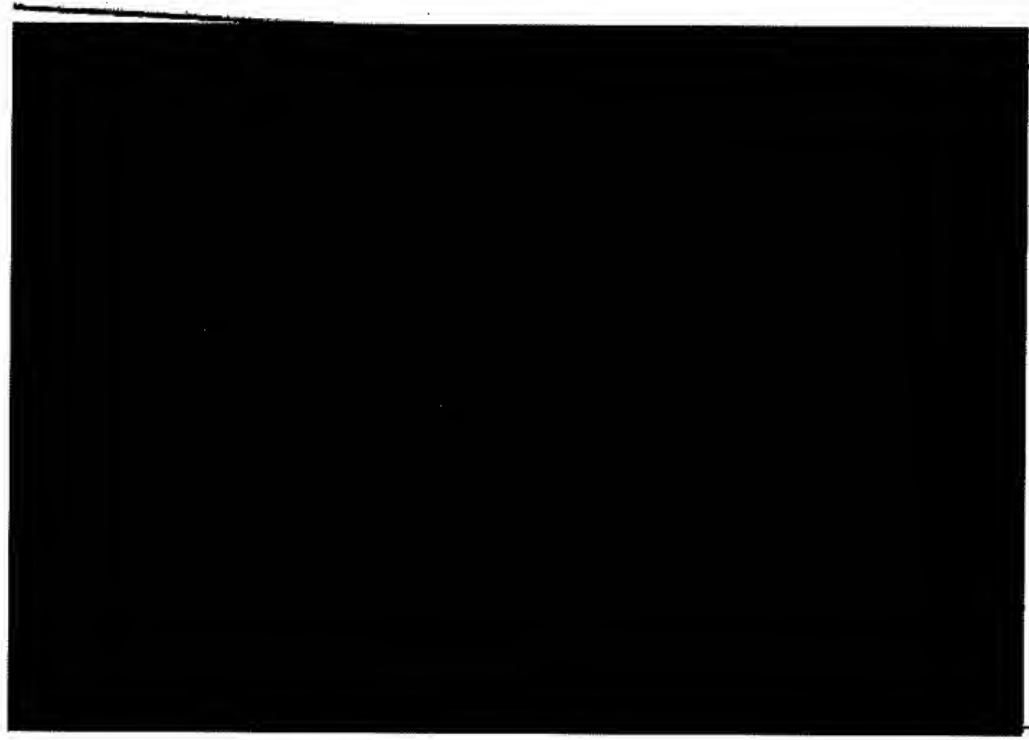
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If continuation sheet 3 of 17

Texas Department of State Health Services
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008127	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703			
(X4) ID PREFIX TAG A 262	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) Continued From page 3		ID PREFIX TAG A 262	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) A 252	(X5) COMPLETE DATE A 252



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If continuation sheet 4 of 17

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Texas Department of State Health Services

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 281	[REDACTED]		A 253	A261 The Clinic Administrator will ensure an staffing requirements are met, including an LVN or RN as part of Direct Patient Care Staff. As outlined in the Texas Administrative Code, Title 25, Chapter 139, Subchapter D, and Section 139.46 (3) Direct Patient Care (B) Nursing Staff. Whole Woman's Health has always been compliant with our staffing and nursing coverage. During the time in question WWH contracted the services of a nursing agency in order to satisfy the nursing requirements by having an LVN at the facility during direct patient care hrs. In addition to having a	02-10-12
A 281	139.46(3)(B) Staffing Requirements		A 281		
	(3) Direct patient care staff				

<p>(B) Nursing staff. The nursing staff shall include a registered nurse(s) or a licensed vocational nurse(s).</p> <p>This Requirement is not met as evidenced by: Based on record review and interview the facility failed to staff the clinic with a registered nurse(s) or a licensed vocational nurse(s).</p> <p>Review of staffing record and personnel records revealed no full time licensed nurse in the facility. Record review revealed a contract agency nurse</p>	<p>was hired on 11-18-11, her Orientation documents, Trainings, Competencies, and Vaccinations have been initiated and are been kept in her personnel file.</p> <p>The Administrator will monitor the completion of nursing staff hiring and training process. Including orientation and training of agency nurses.</p>
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Texas Department of State Health Services		PRINTED: 12/07/2011 FORM APPROVED	
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77705	

(04) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(05) COMPLETE DATE
A 281	Continued From page 3 was being staffed part time in the facility. In reviewing agency nurse's personnel file it was revealed the facility failed to orientate the agency nurse to the abortion facility. An interview with the agency nurse on 11/18/2011 at 5:00 PM, confirmed she worked there part time. She stated "I work for a hospital in Houston thru the agency". An interview with staff #1 (Administrator) on 11/18/2011 at 5:30 PM, confirmed the full time nurse last day worked in the facility was November 3, 2011.	A 281		
A 274	139.47(b)(6) Facility Administration (b) The administrator shall: (5) ensure that staff receive training, education, and orientation to their specific job description, facility personnel policies, philosophy, and emergency procedures in accordance with this section; This Requirement is not met as evidenced by: Based on record review and interview the facility administration failed to ensure staff received training, education, and orientation to their specific job description. A review of the agency nurse's personnel file revealed no documentation the facility administration had orientated the agency nurse to the abortion facility. An interview with staff #1 (Administrator) on 11/18/2011 at 5:30 PM, confirmed the personnel file of the agency nurse contained no documentation the facility had orientated the	A 274	A274 The Administrator will be responsible for ensuring all staff receives training, education, and orientation to their specific job description, facility personnel policies, philosophy, and emergency procedures. The Director of Medical Services has reviewed Administrative responsibilities with the Clinic Administrator to ensure proper follow through of Company Policies. All personnel records, orientation, and proof of follow through of company policies regarding Personnel Records will be completed by 02-10-12, this procedure will also be followed for per diem, agency, and temporary staff. The Administrator will monitor all personnel records in a monthly basis in order to ensure proper maintenance.	02-10-12

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Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 274	Continued From page 8 agency nurse to the Abortion facility.		A 274		
A 283	139.481(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows: (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;		A 283	The Clinic Administrator will ensure the facility's physical and environmental requirements are followed. It is not unusual for office and medical equipment to suffer damage due to the wear and tear of regular use and repairs	

This Requirement is not met as evidenced by:
Based on observation and interview the facility failed to provide a safe and sanitary environment.

Findings Included:

During the tour of the facility on 11/15/2011 at 3:00 PM observed in exam room #1 there was a sign on the bed written it was broken. The bed remained broken during the survey. When questioned the Administrator, she stated someone was to suppose to come fix the bed.

During the tour of the facility on 11/15/2011 at 3:20 PM observed in the procedure room #2 there was a drain in the middle of the room, but the cover was loose and caused a hole to be in the floor right in front of the patient's bed.

During the tour of the facility on 11/15/2011 at 3:20 PM observed in the procedure room #2 there was numerous rusty spots on the suction machine used on the patient for evacuation of the products of conception.

During the tour of the facility on 11/15/2011 at

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are undertaken promptly at WWH. The broken exam table found on exam room #1 was not available for patients until completely repaired and did not affect patient safety in the clinic. The clinic had 2 other exam rooms available for patient care, without hindering the patient's safety at any point. At this point, the exam table has been completely repaired and it is now available for patient care.

The loose cover on the drain on Procedure room #2 will be repaired, as well as the rusted spots on the suction machines. These repairs will be completed by 02-10-12. The Administrator will contract with a medical cleaning company to clean, and buff the floors to address the rust stains that are a natural result of metal equipment seating

OUT011

Texas Department of State Health Services

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FORM APPROVED

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPERVISOR IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 283	Continued From page 7 3:00 PM observed the facility's floor were stained and discolored which gives the appearance of being dirty. During the tour of the facility on 11/15/2011 at 3:00 PM observed the three facility's fire extinguishers were last inspection on March of 2010. During the tour of the facility on 11/15/2011 at 3:00 PM observed no postings of a plan to evacuate the building in case of a disaster. An interview with the administrator on 11/15/2011 at 4:00 PM confirmed the bed was broken in room #1, there was a hole in the in procedure room #2, the floors were stained, and the evacuation plan of the building was not posted for the safety of the patients and employees.		A 283	on vinyl floors throughout the clinic. A fire extinguisher company will be contacted in order to inspect all fire extinguishers for proper functioning. The Administrator will post the emergency evacuation plan throughout the clinic, and will offer a staff training to ensure all personnel is aware of proper emergency evacuation procedure. The Administrator will ensure all equipment it's in optimal functioning and complaint with physical and environmental requirements in order to provide a safe environment for patients.	02-10-12
A 284	139.48(1)(B) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows: (1) A facility shall: (B) equip each procedure room so that procedures can be performed in a manner that assures the physical safety of all individuals in the area;		A 284		
				A284 See correction for A283	

<p>This Requirement is not met as evidenced by: Based on observation and interview the facility failed to provide safe equipment in the patient's procedure rooms.</p> <p>Findings Included:</p> <p>During the tour of the facility on 11/15/2011 at</p>	<p>007011</p>
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Continuation sheet 8 of 17

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF BEAUMONT	STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703	(X4) ID PREFIX TAG A 284	(X5) COMPLETE DATE
SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG A 284	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X6) COMPLETE DATE
Continued From page 8	3:00 PM observed in		

sign on the bed written it was broken. The bed remained broken during the survey. When questioned the Administrator, she stated "someone was to suppose to come fix the bed".

During the tour of the facility on 11/15/2011 at 3:20 PM observed in the procedure room #2 there was numerous rusty spots on the suction machine used on the patient for evacuation of the products of conception.

An interview with the administrator on 11/15/2011 at 4:00 PM confirmed the bed was broken in room #1, and there were numerous rusty spots on the suction machine used on patients for evacuation of the products of conception.

A 286 139.48(1)(D) Physical & Environmental Requirements

The physical and environmental requirements for a licensed abortion facility are as follows.
(1) A facility shall:

(D) have a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility's emergency evacuation protocol required by this subparagraph;

This Requirement is not met as evidenced by: Based on record review and interview the facility failed to conduct and follow the facility's policy on fire and/or disaster drills for evacuation of patients and staff in the facility.

A286

A 286

The Clinic Administrator will be responsible for ensuring all staff is properly trained on the facilities emergency evacuation plan (See Attached)

A staff in service will be facilitated by 02-10-12 in order to train the staff on the Facility's Emergency evacuation plan (Fire, and Natural Disasters)

The Clinic Administrator will ensure an annual Emergency Evacuation Drill has been completed, and documented.

02-10-12

OU7011

K continuation sheet 8 of 17

Texas Department of State Health Services

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 286	<p>Continued From page 8</p> <p>Review of record titled "Fire Safety" revealed "It is the policy of this facility to conduct a fire drill or handle a fire in such a manner to preserve lives, prevent undue panic, and control the spread of fire. Each employee will be aware of fire exits, fire extinguishes, the proper procedure for ensuring fire safety, and the steps to be taken in case of fire. It is not the intent of this policy that any staff member endangers himself; rather, the intent is to ensure the safety both staff and patients."</p> <p>Review of facility records found no evidence of that fire and/or disaster drills had been conducted.</p> <p>An interview with staff #1 (Administrator) on 11/16/2011 at 5:00 PM, confirmed no drills had been conducted in the facility in the last year.</p>		A 286		
				A306	The Clinic Administrator will be responsible for the accurate follow

2007-01-01 Infection Control Standards

(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

This Requirement is not met as evidenced by: Based on observation and interview the facility's staff failed to monitor the expiration dates on sterile supplies.

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A 308

through of the company's Infection control policies (Cleaning, Decontamination, and Sterilization)

02-10-12

All expired supplies were removed from the facility. The Clinic Administrator will inspect supplies inventory to check for expiration dates on a monthly basis, to ensure patient safety. The findings will be submitted to the Director of Medical Services to address any deviations and training needs. Competency of the Administrator and all staff involved in Infection Control Practices will be addresses during QA visits.

OU7011

If continued on sheet 10 of 12

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

(X11) PROVIDER'S SIGNATURE

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(X1) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X2) DATE SURVEY COMPLETED 11/17/2011	
NAME OF PROVIDER OR SUPPLIER 008137 WHOLE WOMANS HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703	
(X4) ID PREFIX TAG A 308	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG A 308	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)
	Continued From page 10 During a tour of the facility on 11/15/2011 at 4:00 PM found in the procedure room #1 and #2, and the supply closet were expired sterile supplies. Size #8 Straight curettes, expired 2011-04 X 48 Size #7 Straight curettes, expired 2011-02 X 1 Size #7 Straight curettes, expired 2011-03 X 8 Size #7 Straight curettes, expired 2011-03 X 8 Size #11 Straight curettes, expired 2011-08 X 15 Size #11 Straight curettes, expired 2011-08 X 8 Size #14 Straight curettes, expired 2011-07 X 28 An interview with staff #1 (Administrator) on 11/15/2011 at 4:00 PM confirmed the sterile supplies from the list above were expired.		
A 334	138.48(d)(5)(F)(iv) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (5) Equipment and sterilization procedures. (F) Biological indicators. (iv) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations. This Requirement is not met as evidenced by: Based on record review and interview the facility failed to read the biological indicators within the 24 hour incubation period on 14 of 54 readings over period of 3 months 8/4/2011-11/15/2011.	A 334	

Manufacturer's recommendations revealed "ProSpore2 is ideal for in-office validation and		SOD - State Form STATE FORM	
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If continuation sheet 11 of 17

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137		(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011	
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703					
(X4) ID PREFIX TAG A 334		SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG A 334		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	
Continued From page 11 monitoring of steam sterilizers and has the same base of use and indications as the ProSpore. It consists of a paper disc carrier containing: Geobacillus stearothermophilus spores. The disc is enclosed in a plastic tube along with a glass vial containing media for growing the bacterial spores. Bromocresol purple has been added to assist in detection		A 334		A334 The Clinic Administrator will be responsible for ensuring all infection Control Standards are followed		(X5) COMPLETE DATE	

spores decrease pH, causing a color change from purple to yellow. A shorter incubation period allows a validated 24 hour result."

Review of record titled "Biological Monitoring log for Prosport2 revealed 14 of 84 readings had been read either before the 24 hour period or over the 24 hour period.

Biological Test Run Date—Biological Test Read Date

8/6/2011	8/8/2011
8/13/2011	8/13/2011
8/13/2011	8/15/2011
8/15/2011	8/15/2011
8/20/2011	8/20/2011
8/22/2011	8/22/2011
8/27/2011	8/28/2011
8/1/2011	8/1/2011
9/10/2011	9/10/2011
9/10/2011	9/12/2011
9/24/2011	9/28/2011
10/8/2011	10/10/2011
10/22/2011	10/24/2011
11/12/2011	11/15/2011

Interview with staff #1 (Administrator) on 11/18/2011 4:00 PM, confirmed the readings were not read according to the manufacturer's recommendations.

A 340 138.48(d)(5)(H)(II) Infection Control Standards

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A 340

007011

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A staff in Service will be facilitated by 02-10-12 to train the staff on Decontamination and Sterilization Procedures. The Clinic Administrator will ensure all instruments have been sterilized, and the Manufacturer's instructions regarding proper reading of bio indicators has been followed, as well as ensuring all sterilization packs and pouches are properly sealed including a Sterilization Indicator Strip on the inside of the packs.

The Clinical Administrator will ensure proper follow through of Decontamination and Sterilization practices as well as all Infection Control Practices. The findings will be submitted to the Director of Medical Services for a period of 90 days in order to address competency, and further training needs.

02-10-12

Texas Department of State Health Services

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 340	<p>Continued From page 12</p> <p>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies.</p> <p>(5) Equipment and sterilization procedures.</p> <p>(H) Maintenance of sterility.</p> <p>(ii) All packages shall be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, this item may not be used. The item shall be returned to sterile processing for reprocessing.</p> <p>This Requirement is not met as evidenced by: Based on observation and interview the facility failed to maintain the sterility of the surgical Instruments.</p> <p>On touring the sterilization area where sterile Instruments are kept, found eight (8) pool pouches sealed and sterilized with open areas still present in the sterile package. Opened a wrapped sterilized Instrument and found no sterilization indicator in the package, continued to open all wrapped Instruments and none of the wrapped Instruments contained sterilization Indicator for steam autoclaves.</p>		A 340	<p>A340</p> <p>See Correction A334</p>	

<p>An interview with staff #2 confirmed she did not know what a sterilization indicator was or what it is used for in the sterilization process nor did she know how to properly seal the peel pouch. Staff #2 on 11/18/2011 at 4:00 PM, asked the surveyor to demonstrate the proper technique on how to seal the packages.</p> <p>An interview with the Administrator on 11/18/2011 at 4:30 PM confirmed there were no sterilization indicators in the facility and observed that staff #2 did not know the proper technique for sealing peel pouches.</p>	<p>SCD - State Form STATE FORM</p>
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<p>Texas Department of State Health Services</p>		<p>PRINTED: 12/07/2011 FORM APPROVED</p>	
<p>STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION</p>	<p>(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137</p>	<p>(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____</p>	<p>(X3) DATE SURVEY COMPLETED 11/17/2011</p>
<p>NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT</p>		<p>STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703</p>	
<p>NAME</p>		<p>DATE</p>	

PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	DATE COMPLETE
A 446	139.58(c) Emergency Services (c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities. This Requirement is not met as evidenced by: Based on record review and interview the facility failed to ensure staff was trained in CPR (cardiopulmonary resuscitation) and follow the facility's policy on 1 (#3) of 4 staff members in the facility. Review of record titled "Job Description Patient Advocate" revealed "Required Continuing Education /Training: 1.) Basic Life Support Certification biennially 2.) Annual OSHA and PPE Inservice training" per the facility's policy. A review of staff #3's personnel record revealed no documentation staff #3 had been trained in CPR. An interview with the Administrator on 11/18/2011 at approximately 1:00 AM, confirmed staff #3 does not have CPR training.	A 446	A446 See Correction A254	
A 476	139.58(j)(1)(E) Anesthesia Services (j) Emergency equipment and supplies appropriate for the type of anesthesia services provided shall be maintained and accessible to staff at all times. (1) Functioning equipment and supplies which	A 476		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED: 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETE DATE
A 478	Continued From page 14 are required for all facilities include: (E) emergency medications specified by the medical staff and appropriate to the type of surgical procedures and anesthesia services provided by the facility. This Requirement is not met as evidenced by: Based on record review, observation, and interview the facility failed to have current emergency medication in the emergency crash cart and follow the facility's policy.	A 478	A476 The Clinic Administrator will be responsible for ensuring all Anesthesia Services requirements are been properly followed. All expired medications have been properly disposed, and the crash cart has been restocked with		

<p>An Inventory of the crash cart revealed expired medication of 50% Dextrose 50 ml vial with expiration date of (September 2011).</p> <p>Review of policy titled "Medication Therapy Practices" revealed:</p> <p>"Medications Inventory and Audit</p> <p>1. Each month the Clinical Coordinator, Nurse or the Administrator will perform a detailed inventory of all medicines and medical supplies in the facility using WWH inventory and tracking tools. (see medicines and medical supplies ordering inventory)</p> <p>2. Each week the Clinical Coordinator, Nurse or Administrator will perform a detailed review and inventory of the crash cart in order to ensure all required medications are current and available. This will include all injectable, tablets and IV solutions, as well as supplies such as syringes, needles, bandages and airways.</p> <p>All expired medications and supplies will be disposed according to WWH wasting medications procedure. (See page 2) the crash cart inventory list will be updated</p>	<p>medications.</p> <p>The Clinic Administrator will be responsible for monitoring the inventory and expiration dates of all crash cart medications. A review of the inventory will be performed on a monthly basis; the findings will be submitted to the Director of Medical Services in order to ensure accuracy. The Director of Medical Services will facilitate a retraining on this policy to the Clinic Administrator by 02-10-12</p>
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008137	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/17/2011
NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH OF BEAUMONT		STREET ADDRESS, CITY, STATE, ZIP CODE 440 18TH ST STE A BEAUMONT, TX 77703			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
A 478	Continued From page 16 complete emergency airway equipment	A 478			
A 498	139.60(h)(6) State and Federal Requirements (h) A licensed abortion facility shall comply with the following federal Occupation Safety and Health Administration requirements: (6) 29 Code of Federal Regulations, Subpart L, §1910.157, concerning portable fire extinguishers.	A 495			
	This Requirement is not met as evidenced by: Based on observation and interview the facility failed to follow the 29 Code of Federal Regulations, Subpart L, 1910.157 concerning portable fire extinguishers.		A495 See Correction A283		
	During the tour of the facility on 11/15/2011 at 3:00 PM observed the three facility's fire extinguishers were last inspection on March of 2010.				
	An interview with the administrator on 11/15/2011 at 4:00 PM confirmed the fire extinguishers were last inspection on March of 2010.				

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Texas Abortion Clinics Marred with Health, Safety Issues, Inspection Reveals

Posted By *Charles Fain Lehman* On October 27, 2017 @ 5:00 am In Issues | [No Comments](#)

New detailed inspection reports reveal dozens of violations of health and safety standards by Whole Woman's Health (WWH), a chain of abortion clinics that says it is "committed to changing the culture around abortion stigma."

The new documents, inspection reports between 2011 and 2017 from the Texas Department of State Health Services, were obtained by And Then There Were None (ATTWN), a nonprofit group that "exists to help abortion clinic workers leave the abortion industry."

The documents show a widespread problem of health violations at WWH clinics. Staff failed to properly disinfect and sterilize equipment used on multiple women, and were not properly trained in the sterilization of surgical instruments. In 2011, the Beaumont, Texas, clinic did not have a registered nurse on staff, in contravention of legal requirements.

The inspector's reports also expressed concerns about maintenance of medical equipment. "There was [sic] numerous rusty spots on the suction machine used on the patient for evacuation of the products of conception," the Beaumont report notes. In multiple cases, supplies and medication were found to be clearly expired.

Facilities themselves were also in disrepair, with floors that were "stained and discolored which gives the appearance of being dirty." A 2016 report on the McAllen, Texas, facility notes a counter so warped it "was no longer a wipeable surface, which could harbor bacteria and infectious matter." The reports also show cracks, rips, and tears on exam tables' covers, and a hole in cabinet flooring that had "the likelihood to allow rodents to enter the facility."

In the most recent report, investigating the Austin facility, investigators found missing stock of fentanyl, the schedule narcotic linked to thousands of overdose deaths.

These reports are part of broader concerns about the safety standards of abortion clinics. According to a report from the pro-life advocacy group Americans United for Life, between 2008 and 2016, 227 abortion clinics, including six Whole Woman's Health clinics, were cited for over 1,400 health and safety deficiencies. These included failures to ensure a "safe and sanitary environment" and failures to properly handle patients' private information.

"Restaurants and tanning salons and vet clinics, they're all more closely regulated than the abortion industry," said Arina Grossu, a bioethicist and the Director of the Center for Human Dignity at the Family Research Council.

Grossu pointed out how regulators and inspectors often look the other way when investigating abortion facilities. Such was true, Grossu said, in the case of abortion doctor and convicted murderer Kermit Gosnell. Pennsylvania state regulators did not inspect Gosnell's facility, out of concerns that inspections would be "putting a barrier up to women" seeking abortions.

"Anyone who cares for women's health and safety should want abortion facilities to be frequently inspected, no matter what their position is on abortion. Because this is a health and safety issue, and just because it has to do with a hot button topic, does not mean that the abortion industry should get a free pass," Grossu told the *Free Beacon*.

Abby Johnson, ATTWN's founder, had previously toured a WWH clinic in Austin, where she documented dirty equipment and what she took to be blood on the walls.

"I was appalled at the state of the Austin Whole Woman's Health. It looked more like a prison than an actual facility where patients went for healthcare. Disgusting does not do it justice," Johnson said.

Johnson, like Grossu, sees these failed health inspections as part of the broader trend of repeated failures of oversight in the abortion industry.

"Laws only matter if they're enforced. And what we see in the abortion industry across the country is that inspections are done, people come in, they're cited for violations, they make a temporary plan to improve, a year later an inspector comes in, they cite them for the same violations, they make a temporary plan to improve ... it's the same cycle, over and over again," she said.

WWH's violations are of particular note because the group was the plaintiff in a case that went all the way to the Supreme Court in a successful effort to ensure that abortion clinics were not required to meet high medical standards.

In 2013, the Texas State Legislature passed, and then-Gov. Rick Perry (R.) signed, H.B. 2. Among other limits on abortion, the bill imposed requirements that physicians at abortion clinics have admitting privileges at a hospital within 30 miles of the clinic; that they provide a 24-hour contact number for patients to reach them at; and that abortion clinics meet the health and safety standards of ambulatory surgical centers, a particular kind of clinic that provides surgeries as an alternative to hard-to-access hospitals.

"If we're going to say that we're for women, and we're for protecting women, then this was sort of a common sense measure," Johnson said.

Johnson, who lobbied for the bill, noted that many of the Planned Parenthood centers opened in Texas since the passage of H.B. 2 met the ambulatory surgical center standards voluntarily. However, WWH decided that the health and safety requirements were unconstitutionally burdensome.

WWH brought suit, alleging that H.B. 2 violated it and its clients' constitutional rights. The state of Texas responded that it was simply trying to ensure the health and safety of its female citizens. That suit eventually came before the Supreme Court which, in a 5-3 decision, agreed with WWH.

"The Texas law called H. B. 2 inevitably will reduce the number of clinics and doctors allowed to provide abortion services.... it is beyond rational belief that H. B. 2 could genuinely protect the health of women, and certain that the law 'would simply make it more difficult for them to obtain abortions,'" wrote Justice Ruth Bader Ginsburg in a brief concurrence.

Justice Samuel Alito, for his part, warned that the court's rush to support abortion rights meant that it failed to adequately investigate the surgical center requirements as anything but a "package," leading to the striking down of obvious and constitutionally sound safety measures.

"Provisions that are indisputably constitutional—for example, provisions that require facilities performing abortions to follow basic fire safety measures—are stricken from the books. There is no possible justification for this collateral damage," Alito wrote.

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Charles Fain Lehman

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Charles Fain Lehman is a staff writer for the Washington Free Beacon. He writes about policy, especially crime, law, drugs, and social issues. Reach him on twitter (@CharlesFLehman) or by email at lehman@freebeacon.com.

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Exhibit 7.1
Legal Opinion to ISDH

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Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 10/21/2016
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
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A 000	TAC 139 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An unannounced visit was made on the morning of 10/20/2016 to conduct a Re-licensure Survey to determine compliance with 26 TAC Chapter 139 State Licensing Rules for Abortion Facility. An entrance conference was conducted with the Director of Clinic Services. The purpose of the visit and procedure for the survey was discussed. An exit conference was conducted on 10/21/16 with the Director of Clinic Services. Deficiencies were cited. The facility's personnel was given an opportunity to provide additional information and ask questions.	A 000	Accepted 11/8/16	
A 149	TAC 139.44(b)(3)(A)(B)(C)(D) Orientation/Training/Demonstrated Competency (3) the employee understands, at a minimum but not limited to, the following: (A) coordination and treatment of patient care; (B) sterilization and infection control policies; (C) patient education/information; (D) informed consent policies;	A 149	A.149 The Clinic Administrator will be responsible for ensuring all personnel working in the pathology lab has gone through the appropriate orientation process, training and demonstrate competency on decontamination and sterilization techniques.	11/30/16

SOD - State Form
LABOR

STATE

IDENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Director of Clinical Services

11/5/16 12/08/16

JME311

If continuation sheet 1 of 22

Texas Department of State Health Services

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Texas Department of State Health Services

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A 149	<p>Continued From page 2</p> <p>A review of the autoclave load log from 9/29/2015 thru 10/19/2015 revealed no temperature, time, or pressure recorded on the log.</p> <p>A review of the record titled, "Whole Women's Health Pathology Training Checklist" revealed the only record of training for Staff #3. There was no training on sterilization of sterile instruments.</p> <p>Review of the policy titled, "Procedure Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" revealed the following:</p> <p>"Maintenance of Sterility Items that are packaged properly will remain sterile unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of being compromised. Commercially packaged items will be considered sterile according to the manufacturer's instructions. A. All packages will be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item will be returned to the sterile area for reprocessing/sterilizing. B. The indicator tape on the outside and on the inside of the pack will be checked before the instruments are used. If the indicator tape did not change the pack will be returned to the sterile area for reprocessing/sterilizing. The other packs/pouches from that load will be checked. C. If instruments are ("flash") sterilized unwrapped an indicator tape or strip will be placed in the tray and presented to the providing MD along with the instrument. D. Sterilized items will be handled in a manner that does not compromise the packaging of the product.</p>	A 149		

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A 149	Continued From page 3 E. Sterilized items will be transported as to maintain cleanliness and sterility and to prevent physical damage. F. Sterilized items will be stored in the sterile area. This area has controlled ventilation and has restricted access. G. Sterilized items will be packed in the sterilizers and positioned so the packaging is not crushed, bent, compressed, or punctured in order to ensure the packages' sterility." An interview with Staff #3 on 10/20/2015 at approximately 3:00 PM confirmed the above findings and the policy was not being followed. Staff #3 was asked what type of training have you had on the sterilization of instruments. Staff #3 stated, "I just shadowed someone for couple of days." The interview with Staff #3 revealed the staff member was still not knowledgeable in the proper procedure of sterilizing instruments.	A 149		
A 197	TAC 139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to provide safe and sanitary environment.	A 197	A197 The Clinic Administrator will be responsible for ensuring the physical and environmental requirements for the facility are strictly followed.	11/30/15

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A 197	Continued From page 4 During the tour of the facility on 10/21/2015 at approximately 10:00 AM the following environmental issues were observed: The findings included: Laboratory Area: Patient lab supplies were being stored under the sink in the Lab room. Observed a brown substance on patients' supplies and on the floor of the sink shelf which appeared to be a leak. Pathology Room: Observed some type of soap being stored in the bag out of the original container on the pathology sink. There was water on the cabinet surface where instruments are placed to dry. The Administrator laid her phone down on the cabinet in the water during the tour and stated "Oh that's wet." In the Pathology room beside the Biohazard container in a card board box sitting on the floor was the blue wrap for the surgical instruments. In the pathology room (what the facility calls the sterile side) was another box of the blue wrap in a card board box sitting on the floor. The products of conception were being examined and contaminated instruments were being washed in this same room. The width of area discussed was approximately 3 feet that separated clean from dirty. A fan was sitting on top of the surgical trays on the shelf, the under the cabinet in the Pathology room. In the Pathology room 15 gallons of Cidex, Enzymatic solution, and bleach were being stored	A 197	Laboratory Area: All patient supplies have been removed from the cabinet under the sink, and have been stored in a plastic container on a separate cabinet. The packaging that was stained with betadine "brown substance" has been removed from the lab and properly disposed. An infection control training outlining the proper method to store laboratory supplies was facilitated for staff on 11/11/15, and the records have been failed in the each staff's personnel record. Recovery Room: The oxygen tank has been moved to a safer place away from risk of being knocked down by patients, visitors, or staff. Laundry Room: The Laundry room has been re organized with the intent of maintaining a clear separation between the dirty linens, and the clean laundry. All janitorial supplies have been properly stored in a closet designated for janitorial supplies. Physical walk through of the facility: The exam tables, and suction machines will be refurbished to address the peeling paint, and the ceiling tile with the 3 inch water mark in the lab will be replaced.	11/11/15 11/11/15 11/12/15 11/30/15

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A 197	<p>Continued From page 5</p> <p>directly on the floor.</p> <p>Patient Storage Closet:</p> <p>In the patient care closet, where patient supplies are stored it was observed there were sanitary pads on the floor. Dust particles were on the floor next to the sanitary pads along with a biohazard sharps container and card board boxes. The patient supplies were open on the shelves, and it was observed that there were card board shipping boxes on the shelves beside the open patient supplies. Also, there were card board shipping boxes stored on top of the open patient supplies. Card board boxes can harbor parasites, insects, and microorganisms.</p> <p>"External shipping containers have been exposed to unknown and potentially high microbial contamination. Also, shipping cartons, especially those made of corrugated material; serve as generators of and reservoirs for dust." (AAM1 ST46-Section 5.2 Receiving items).</p> <p>Recovery Room:</p> <p>During the tour of the recovery room on 10/20/2015 at 3:00 PM observed 2 card board shipping boxes on the floor of the recovery room. The boxes were full of patients' supplies (blue pads). The lid was open to the boxes making it available for contaminants to enter the boxes.</p> <p>There was an oxygen tank sitting on the floor in the recovery area with a holder. The oxygen tank was beside the water fountain, which made it accessible to be knocked over by staff, patients, and family members.</p> <p>An interview with Staff #1 on 10/20/2015 at 3:00 PM confirmed the above findings.</p>	A 197	<p>In order to monitor compliance with the physical and environmental requirements for the facility, the Administrator will perform a walk-through of the physical plant on a weekly basis to ensure all supplies are properly stored, and equipment and instruments are in optimum condition.</p>	

- Washington Free Beacon - <http://freebeacon.com> -

Texas Abortion Clinics Marred with Health, Safety Issues, Inspection Reveals

Posted By *Charles Fain Lehman* On October 27, 2017 @ 5:00 am In Issues | [No Comments](#)

New detailed inspection reports reveal dozens of violations of health and safety standards by Whole Woman's Health (WWH), a chain of abortion clinics that says it is "committed to changing the culture around abortion stigma."

The new documents, inspection reports between 2011 and 2017 from the Texas Department of State Health Services, were obtained by And Then There Were None (ATTWN), a nonprofit group that "exists to help abortion clinic workers leave the abortion industry."

The documents show a widespread problem of health violations at WWH clinics. Staff failed to properly disinfect and sterilize equipment used on multiple women, and were not properly trained in the sterilization of surgical instruments. In 2011, the Beaumont, Texas, clinic did not have a registered nurse on staff, in contravention of legal requirements.

The inspector's reports also expressed concerns about maintenance of medical equipment. "There was [sic] numerous rusty spots on the suction machine used on the patient for evacuation of the products of conception," the Beaumont report notes. In multiple cases, supplies and medication were found to be clearly expired.

Facilities themselves were also in disrepair, with floors that were "stained and discolored which gives the appearance of being dirty." A 2016 report on the McAllen, Texas, facility notes a counter so warped it "was no longer a wipeable surface, which could harbor bacteria and infectious matter." The reports also show cracks, rips, and tears on exam tables' covers, and a hole in cabinet flooring that had "the likelihood to allow rodents to enter the facility."

In the most recent report, investigating the Austin facility, investigators found missing stock of fentanyl, the schedule narcotic linked to thousands of overdose deaths.

These reports are part of broader concerns about the safety standards of abortion clinics. According to a report from the pro-life advocacy group Americans United for Life, between 2008 and 2016, 227 abortion clinics, including six Whole Woman's Health clinics, were cited for over 1,400 health and safety deficiencies. These included failures to ensure a "safe and sanitary environment" and failures to properly handle patients' private information.

"Restaurants and tanning salons and vet clinics, they're all more closely regulated than the abortion industry," said Arina Grossu, a bioethicist and the Director of the Center for Human Dignity at the Family Research Council.

Grossu pointed out how regulators and inspectors often look the other way when investigating abortion facilities. Such was true, Grossu said, in the case of abortion doctor and convicted murderer Kermit Gosnell. Pennsylvania state regulators did not inspect Gosnell's facility, out of concerns that inspections would be "putting a barrier up to women" seeking abortions.

"Anyone who cares for women's health and safety should want abortion facilities to be frequently inspected, no matter what their position is on abortion. Because this is a health and safety issue, and just because it has to do with a hot button topic, does not mean that the abortion industry should get a free pass," Grossu told the *Free Beacon*.

Abby Johnson, ATTWN's founder, had previously toured a WWH clinic in Austin, where she documented dirty equipment and what she took to be blood on the walls.

"I was appalled at the state of the Austin Whole Woman's Health. It looked more like a prison than an actual facility where patients went for healthcare. Disgusting does not do it justice," Johnson said.

Johnson, like Grossu, sees these failed health inspections as part of the broader trend of repeated failures of oversight in the abortion industry.

"Laws only matter if they're enforced. And what we see in the abortion industry across the country is that inspections are done, people come in, they're cited for violations, they make a temporary plan to improve, a year later an inspector comes in, they cite them for the same violations, they make a temporary plan to improve ... it's the same cycle, over and over again," she said.

WWH's violations are of particular note because the group was the plaintiff in a case that went all the way to the Supreme Court in a successful effort to ensure that abortion clinics were not required to meet high medical standards.

In 2013, the Texas State Legislature passed, and then-Gov. Rick Perry (R.) signed, H.B. 2. Among other limits on abortion, the bill imposed requirements that physicians at abortion clinics have admitting privileges at a hospital within 30 miles of the clinic; that they provide a 24-hour contact number for patients to reach them at; and that abortion clinics meet the health and safety standards of ambulatory surgical centers, a particular kind of clinic that provides surgeries as an alternative to hard-to-access hospitals.

"If we're going to say that we're for women, and we're for protecting women, then this was sort of a common sense measure," Johnson said.

Johnson, who lobbied for the bill, noted that many of the Planned Parenthood centers opened in Texas since the passage of H.B. 2 met the ambulatory surgical center standards voluntarily. However, WWH decided that the health and safety requirements were unconstitutionally burdensome.

WWH brought suit, alleging that H.B. 2 violated it and its clients' constitutional rights. The state of Texas responded that it was simply trying to ensure the health and safety of its female citizens. That suit eventually came before the Supreme Court which, in a 5-3 decision, agreed with WWH.

"The Texas law called H. B. 2 inevitably will reduce the number of clinics and doctors allowed to provide abortion services.... it is beyond rational belief that H. B. 2 could genuinely protect the health of women, and certain that the law 'would simply make it more difficult for them to obtain abortions,'" wrote Justice Ruth Bader Ginsburg in a brief concurrence.

Justice Samuel Alito, for his part, warned that the court's rush to support abortion rights meant that it failed to adequately investigate the surgical center requirements as anything but a "package," leading to the striking down of obvious and constitutionally sound safety measures.

"Provisions that are indisputably constitutional—for example, provisions that require facilities performing abortions to follow basic fire safety measures—are stricken from the books. There is no possible justification for this collateral damage," Alito wrote.

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Charles Fain Lehman

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Charles Fain Lehman is a staff writer for the Washington Free Beacon. He writes about policy, especially crime, law, drugs, and social issues. Reach him on twitter (@CharlesFLehman) or by email at lehman@freebeacon.com.

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Exhibit 7.1
Legal Opinion to ISDH

PRINTED: 12/29/2016
FORM APPROVED

Texas Department of State Health Services

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[Signature]
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11/5/16 12/08/15

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Texas Department of State Health Services

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO			STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
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A 149	Continued From page 3 E. Sterilized items will be transported as to maintain cleanliness and sterility and to prevent physical damage. F. Sterilized items will be stored in the sterile area. This area has controlled ventilation and has restricted access. G. Sterilized items will be packed in the sterilizers and positioned so the packaging is not crushed, bent, compressed, or punctured in order to ensure the packages' sterility." An interview with Staff #3 on 10/20/2015 at approximately 3:00 PM confirmed the above findings and the policy was not being followed. Staff #3 was asked what type of training have you had on the sterilization of instruments. Staff #3 stated, "I just shadowed someone for couple of days." The interview with Staff #3 revealed the staff member was still not knowledgeable in the proper procedure of sterilizing instruments.	A 149			
A 197	TAC 139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to provide safe and sanitary environment.	A 197	A197 The Clinic Administrator will be responsible for ensuring the physical and environmental requirements for the facility are strictly followed.	11/30/15	

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A 197	<p>Continued From page 5</p> <p>directly on the floor.</p> <p>Patient Storage Closet:</p> <p>In the patient care closet, where patient supplies are stored it was observed there were sanitary pads on the floor. Dust particles were on the floor next to the sanitary pads along with a biohazard sharps container and card board boxes. The patient supplies were open on the shelves, and it was observed that there were card board shipping boxes on the shelves beside the open patient supplies. Also, there were card board shipping boxes stored on top of the open patient supplies. Card board boxes can harbor parasites, insects, and microorganisms.</p> <p>"External shipping containers have been exposed to unknown and potentially high microbial contamination. Also, shipping cartons, especially those made of corrugated material; serve as generators of and reservoirs for dust." (AAM1 ST46-Section 5.2 Receiving items).</p> <p>Recovery Room:</p> <p>During the tour of the recovery room on 10/20/2015 at 3:00 PM observed 2 card board shipping boxes on the floor of the recovery room. The boxes were full of patients' supplies (blue pads). The lid was open to the boxes making it available for contaminants to enter the boxes.</p> <p>There was an oxygen tank sitting on the floor in the recovery area with a holder. The oxygen tank was beside the water fountain, which made it accessible to be knocked over by staff, patients, and family members.</p> <p>An interview with Staff #1 on 10/20/2015 at 3:00 PM confirmed the above findings.</p>	A 197	<p>In order to monitor compliance with the physical and environmental requirements for the facility, the Administrator will perform a walk-through of the physical plant on a weekly basis to ensure all supplies are properly stored, and equipment and instruments are in optimum condition.</p>	

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A 197	<p>Continued From page 6</p> <p>Laundry Room:</p> <p>During a tour of the facility on 10/20/15 and 10/21/15 of the survey card board shipping boxes were stored in front of the (2) soiled linen hampers on the floor in the laundry area. There were 4 boxes which contained paper towels and bathroom tissue stacked in front of the soiled linen hamper, and the washer and dryer. In this same area across from the soiled linen cart (approximately 3 feet) was an open wire rack where patient gowns, physicians' scrubs, and patient blankets were being stored. There were no barriers on the bottom shelf and no cover over the shelving. On the shelf with the clothing items was an autoclave. Above the patient gowns, physicians' scrubs, and patient blankets were package of paper towel rolls. There was clothing articles piled on top of the dryer along with boxes of fabric softener. Beside the dryer was another soiled linen hamper that had a shipping box on top of the linen hamper. Observed that all 3 linen hampers had soiled linen in them. The linen hampers were all labeled with biohazard label. This laundry area stayed cluttered with shipping boxes and observed that none of the staff members had ever moved or cleaned the area during the 2 day survey.</p> <p>An interview with Staff #1 on 10/21/2015 at approximately 12:00 PM confirmed the above findings. Staff #1 stated, "The boxes are here because we just got supplies."</p> <p>Observed no change in the laundry area during the survey dates of 10/20-21/2015.</p> <p>Tour of the facility on 10/20/15, the following observations were made:</p> <p>-Through out the facility, base boards were lifting</p>	A 197		

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A 197	Continued From page 7 at some of the seams and "yellowing dirt" was observed along the base of the baseboards. - In the recovery room, the exam table had rust around each drawer and around the drawer handles. - In the procedure room- Amella: the drawers of the exam table had rust and peeling paint. -In the procedure room -Georgia: The emesis basins, used for patients, were stored under the sink. The suction machine, the bumper around the machine had fallen off the machine and was covered in dust. In the Lab room: A ceiling tile had water damage. -The crash cart in the hallway of the facility was covered in dust. Interview on 10/20/15 with the staff S#1, confirmed the above findings.	A 197		
A 213	TAC 139.49(b)(1)(A)(I)(II) Infection Control Standards (A) An abortion facility shall ensure that all staff comply with universal/standard precautions as defined in this paragraph. (i) Universal/standard precautions includes procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments. (ii) Universal/standard precautions synthesize the major points of universal precautions with the points of body substance precautions and apply them to all patients receiving care in facilities,	A 213	A213 The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed. Whole Woman's Health of San Antonio has developed a performance record for the usage of Manual Vacuum Aspirator (MVA) in order to track the usage and performance of the MVA's in rotation. (See log attached)	11/30/15

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A 213	<p>Continued From page 8</p> <p>regardless of their diagnosis or presumed infection status.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain performance records for the usage of the Manual Vacuum Aspiration (handheld syringe used for manual evacuation for an abortion). Also, the facility failed to follow their own policy processing the Ipas MVA Plus.</p> <p>A review of records revealed no documentation that the facility was keeping records of how many times the MVA had been used.</p> <p>A review of the manufactures' guideline on the Ipas MVA revealed the following: "Providers can choose the disinfectant/sterilization method that best results their practice. As a guideline, the Ipas MVA Plus can be used between 25-50 times when following the Ipas processing instructions provided in its package insert. Whichever method of disinfection/ sterilization is chosen, the Ipas MVA needs to be inspected before next use. If the Ipas MVA plus shows signs of damage or is not functioning properly, it should be discarded." During a tour of the facility on 10/20/2015 at 10:50 AM observed multiple MVA's on the counter at the nursing station in an open container with no lid. Also, observed a MVA lying on the second shelf of a rolling cart. The MVA was lying on an open surface with no cover over the MVA. The cart was used to carry supplies in and out of the procedure room. A review of the facility policy titled, "Procedure Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" revealed the</p>	A 213	<p>The medical director will conduct an inspection of all MVA's in rotation to assess their current condition and need for replacement. This audit will be documented and kept in the performance record binder. All MVA's devises will be stored in a closed plastic container before use.</p> <p>A staff training will be provided by the Director of Clinical Services to ensure the staff understand the process to decontaminate and sterilize these devises, as well as the steps to inspect them before use and document the number of times it is used.</p> <p>In order to ensure compliance with this requirement, the Clinic Administrator will conduct a monthly audit of the performance record log as well as the condition of the MVA's.</p>	

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A 213	Continued From page 9 following: "Cleaning and Processing the Ipas MVA Plus: *Clean it by washing all surfaces thoroughly in warm water and detergent. Detergent is preferable to soap, which can leave a residue. As an alternative, an enzymatic cleaner, a solution specifically designed to clean blood and tissue from surgical instruments, can be used. *For a high-level disinfectant soak, place all the parts in the soak for the amount of time directed on the bottle. Ipas recommends Cidex or Cidex OPA, or Sporox II, however, Cidex OPA is the Facility's approved disinfectant soak. Ipas MVAs must soak in Cidex OPA for at least 12 minutes. *The Ipas MVA Plus can be used between 25 and 50 times when following the Ipas processing instructions. The Ipas MVA should always be inspected before next use, and should be discarded at any signs of damage or is not functioning properly. *Aspirators need to be stored in dry, covered containers or packages to protect them from dust and other contaminants." An Interview with Staff #1 on 10/21/2015 at 10:30 AM confirmed the facility was not keeping a record of how many times the MVA had been used.	A 213			
A 242	TAC 139.49(d)(5)(D)(i)(ii) Infection Control Standards D) Packaging. (I) All wrapped articles to be sterilized shall be	A 242	A242 The Clinic Administrator will be responsible for ensuring all infection control standards are being followed by ensuring the sterilization procedure is strictly monitored.	10/22/15 11/30/15	

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A 242	<p>Continued From page 10</p> <p>packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs shall be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays shall not exceed 17 pounds.</p> <p>(ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to document on the instrument packages the following: the date and time of sterilizing, sterilizing load number, and the identification of the autoclave used.</p> <p>Observed during the tour of the sterilization room on 10/20/2015 at approximately 10:14 AM the peel pouches in the plastic container and the peel pouches that were being removed from the autoclave were not labeled with date and time sterilized, sterilizing load number, and the identification of the autoclave used. The wrapped instruments that were removed from the autoclave were not labeled with date and time sterilized, sterilizing load number, and the identification of the autoclave used.</p> <p>An interview with the Staff #3 on 10/20/2015 at 11:00 AM confirmed the above findings.</p>	A 242	<p>All instruments have been re sterilized and the date, time, load # and autoclave ID has been documented on each pouch and pack.</p> <p>The Director of Clinical services will facilitate an infection control training on November 30th, 2015 staff will be required to prepare for this training by reading WWH policy for decontamination and Sterilization techniques. During the training, the designated trainer will show the staff the proper way to wrap, pack, and label instruments to be sterilized. By the end of the training the staff will be asked to perform each one of these steps while evaluated by the trainer. A competency checklist will be documented and filed in the staff's personnel record.</p> <p>In order to ensure compliance, the Clinic Administrator will perform randomized tracer to address staff's competency and follow through of our policies and address training needs.</p>	11/30/15
A 245	TAC 139.49(d)(5)(F)(iii)(iv)(v) Infection Control Standards	A 245		11/30/15

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A 245	<p>Continued From page 11</p> <p>(F) Biological indicators. (iii) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load. (iv) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations. (v) All available items shall be recalled and reprocessed if a sterilizer malfunction is found. A list of all items which were used after the last negative biological indicator test shall be submitted to the administrator.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain a log for biological indicators (BI) that included time, load identification, and contents of the load. Also, the facility failed to follow their own policy.</p> <p>Findings include:</p> <p>Observation on 10/20/2015 at 10:15 AM revealed a "Pathology" room with one (1) Pelton Delta Q autoclave.</p> <p>An interview with Staff #3 on 10/20/2015 at 10:15 AM stated she was a medical assistant and the person responsible for the autoclave. Staff #3 stated, "I run a biological indicator (BI) test with the 1st load every day that the autoclave is ran."</p> <p>A review of the record titled, "Biological Indicator Log" on 10/20/2015 at 11:00 AM revealed the following: the time the biological was placed in the autoclave was left blank and the time the</p>	A 245	<p>A245</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are met by ensuring the Biological Indicator (BI) log is completed and accurate.</p> <p>All BI test performed after the survey conducted on 10/21/15 have been accurately documented on the BI log to include time and load ID, contents, and the 24 hr reading with the time it was run.</p> <p>The Director of Clinical Services will facilitate a training for all staff working in the pathology lab on how to run biological indicators (BI) and how to properly document the test and results of the spore test. The Director of Clinical Services will observe each staff run the BI test and document it on the log.</p> <p>The Clinic Administrator will monitor compliance with this standards by conducting an audit of the sterilization and BI logs on a monthly basis to ensure adequate competency, and address training needs.</p>	<p>11/30/15</p> <p>10/21/15</p>

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A 245	Continued From page 12 biological was read 24 hours later was left blank. Also, the load identification and contents of the load was not documented on the biological log. A review of the log for the date 9/30/2015 revealed the control biological was left blank. A review of facility policy titled, "Procedure for Pathology" revealed the following: "Biological Indicators The efficacy of the sterilizing process will be monitored with reliable biological indicators. (i.e. Bacillus stearothermophilus) appropriate for the type of sterilizer used. A. These indicators will be included in one run each day of use per sterilizer. B. A log will be maintained with the load identification, biological indicator results, and identification of the contents of the load. C. If a test is positive, the sterilizer will immediately be taken out of service and will not be put back into service until it has been serviced and successfully tested. D. All available items will be recalled and reprocessed if a sterilizer malfunction is found." An interview on with Staff #3 on 10/20/2015 at 10:15 AM revealed the biological log was not completed and facility policy had not been followed.	A 245			
A 247	TAC 139.49(d)(5)(H)(i)(ii)(iii) Infection Control Standards (H) Maintenance of sterility. (i) Items that are properly packaged and sterilized shall remain sterile indefinitely unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of	A 247	A 247 The Clinic Administrator will be responsible for ensuring all Infection Control Standards are accurately followed by ensuring medication therapy protocol is followed.	11/30/15	

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A 247	Continued From page 13 being compromised. (ii) Medication or materials within a package that deteriorate with the passage of time shall be dated according to the manufacturer's recommendations. (iii) All packages shall be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item may not be used. The item shall be returned to sterile processing for reprocessing. This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to discard medication not administered in a timely manner. During a tour of the facility with the Administrator on 10/21/2015 at 9:46 AM observed a syringe on the second shelf of a rolling cart in the Pathology room. There were no staff members in the room. The Administrator was asked what is that syringe for and why was the syringe left unattended. The Administrator stated, "It was for today's procedure." Surveyor showed the syringe to the Administrator and the syringe was labeled "Lidocaine 10/20/2015." The syringe had been left from the the previous day procedures. An interview with the Administrator on 10/21/2015 at 9:46 AM confirmed the above findings.	A 247	The unused lidocaine syringe found on the rolling cart in the pathology room from the previous surgery day was immediately disposed of. The Clinical coordinator performed a thorough check of all procedure rooms, pathology lab and nurse's station to ensure there are no unused medications. An in service will be facilitated to all surgical staff in order to ensure their understanding on the proper way to prepare medications for each day of services, and how to dispose of all unused medications at the end of session. The Clinical Coordinator will be responsible for ensuring this practice is strictly followed, by conducting an end of day walk through and check of each procedure room, pathology lab, and nurses station. Findings will be immediately communicated to the Clinic Administrator.	11/30/15 12/9/15
A 249	TAC 139.49(d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall ensure proper storage and handling of items in a manner that does not compromise the packaging of the product. (i) Sterilized items shall be transported so as to	A 249	A249 The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed.	

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A 249	<p>Continued From page 14</p> <p>maintain cleanliness and sterility and to prevent physical damage.</p> <p>(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.</p> <p>(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.</p> <p>(iv) Storage of supplies shall be in areas that are designated for storage.</p> <p>This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to store peel pouches in a position that was free of being crushed, bent, compressed, or punctured.</p> <p>FINDINGS:</p> <p>During a tour of the facility on 10/20/2015, multiple peel pouches were stored in a plastic container in the pathology room. Also, the peel pouches were found in a blue tote bag on a rolling cart that was used for storage of the sterile instruments.</p> <p>Approximately 20 peel packs were crushed and compressed in the plastic container which had no lid and was stored in the pathology room, where products of conception were examined and contaminated instruments were washed. The facility had no area designated for storage of sterile peel pouches.</p> <p>An interview with Staff #3 on 10/20/2015 at approximately 11:00 AM confirmed the above findings.</p>	A 249	<p>The Clinic Administrator along with the staff trained to work in the pathology and sterilization lab, have reorganized the area and identified storage space outside of the pathology and sterilization room. They have designated storage space on the surgical hall closet in order to adequately stack sterilized pouches in a position free of being crushed, bent, compressed or punctured.</p> <p>In addition a staff in service will be facilitated to ensure staff understands how to properly store packs and pouches.</p> <p>In order to monitor compliance with this requirement, the Clinic Administrator will conduct random weekly inspections of the sterilized stored instruments. Findings will be addressed during quality assurance meetings.</p>	

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A 255	Continued From page 15	A 255		
A 255	<p>TAC 139.49(d)(5)(K)(I)(II)(III) Infection Control Standards</p> <p>(K) Disinfection.</p> <p>(i) The manufacturer's written instructions for the use of disinfectants shall be followed.</p> <p>(ii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.</p> <p>(iii) Disinfectant solutions shall be kept covered and used in well-ventilated areas.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to follow the manufacturer's written instructions for the use of cold disinfectant (Cidex) utilized on surgical instruments. Also, the facility failed to provide a disinfectant log for the Cidex being utilized in the facility for the disinfection of surgical instruments.</p> <p>Findings:</p> <p>During the tour of the Pathology room on 10/21/21 at 9:47 AM revealed a large clear plastic container labeled Cidex. The container was covered, but there was no label to indicate when the Cidex was mixed. Also, under the sink in the pathology room was a gallon of open Cidex with no label as to when the container was open. There was a glass suction jar ¾ full with a green liquid substance and written on the side of the glass jar was Cidex. There was no label or date as to when the liquid substance was mixed.</p> <p>During the tour of the Pathology room (where cold disinfectant was located) on 10/20/2015 at</p>	A 255	<p>A255</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are being followed by ensuring the proper labeling and documenting of decontaminating solutions.</p> <p>Whole Woman's Health of San Antonio uses the Metrex disinfection log which contains all the information required by the manufacturer's instructions. (See Attached)</p> <p>This log tracks the date solution prep, expiration and staff preparing solution, this log is kept on a binder labeled Cidex OPA Plus log, and a memorandum directing staff to document on the solution's original container the date it was opened, and when it expires according to the manufacturer's instructions will be included in this binder as well as circulated during the infection control training scheduled for 11/30/15</p>	11/30/15

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 10/21/2015
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NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO	STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 255	<p>Continued From page 16</p> <p>10:45, Staff #3 was asked where the cold disinfectant log was. Staff #3 stated, "I don't have a disinfectant log." During a tour of the Pathology room on 10/21/2015 at 9:50 AM, a disinfectant log was observed, but the log was blank.</p> <p>A review of the log titled, "Solution Testing log Sheet for: MetriCide OPA" revealed the date solution was opened was 10/9/2015 and the expiration date was 12/23/2015. The OPA-Cidex is only stable for 14 days from day the solution is mixed. This log location/department was written as Path room/Sonography. Staff #3 was asked on 10/20/2015 at 10:45 AM what was the green substance in the glass jar under the sink in the Pathology room. Staff #3 stated, "I don't know that belongs to the sonographer."</p> <p>A review of the manufactures' guideline revealed the following: "CIDEX OPA Solution may be reused for up to a Maximum of 14 days provided the required conditions of ortho-phthalaldehyde concentration and temperature exist based upon monitoring described in the Direction for use. Do not rely solely on day in use. Concentration of this product during its reuse life must be verified by the CIDEX OPA Solution Test Strips prior to each use to determine that the concentration of ortho-phthalaldehyde is above the MEC of 3%. The Product must be discarded after 14 days. Use CIDEX OPA Solution in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb ortho-phthalaldehyde from the air."</p> <p>A review of the manufactures' guideline on the</p>	A 255	<p>The Cidex solution currently in use by the pathology staff has been placed in a container with a tight lid. The Cidex used to disinfect the ultrasound transducer will be placed in a glass jar labeled with date the solution was prepared and the expiration date.</p> <p>In order to ensure compliance with this requirement the Administrator will conduct a monthly audit of the Cidex log and a walk through of the pathology room to ensure this solution is properly stored and labeled.</p>	

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 255	Continued From page 17 OPA gallon container revealed the following: "Usage: NO ACTIVATION IS REQUIRED. Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container may be stored for up to 75 days (providing the 75 days does not extend past the expiration date on the container) until used. Record the date the solution was poured out of the original container into a secondary container in a log book (separate from the one mentioned above), or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 14 days. The product must be discarded after 14 days even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC (Minimum Effective Concentration)." An interview with the Staff #1 on 10/21/2015 at 11:00 AM confirmed the above findings.	A 255		
A 257	TAC 139.49(d)(5)(L)(II)(I - V) Infection Control Standards (L) Performance records. (II) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include: (I) the sterilizer identification; (II) sterilization date and time; (III) load number; (IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts); (V) Identification of operator(s);	A 257	A257 The clinic administrator will be responsible for ensuring all infection control standards are strictly followed by ensuring the Autoclave Load Log is completed and adequately tracks the performance of the autoclave.	11/30/15

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 10/21/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 257	Continued From page 18 This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain performance records for the autoclave during operation that included pressures, temperatures, and times at desired temperature and pressure. Findings include: Observation on 10/20/2015 at 10:15 AM revealed a "Pathology" room with one (1) Pelton Delta Q autoclave. An interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclave. A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the load identification, date, time, duration and temperature of exposure phase during the operational phase of the autoclave. A continued interview with Staff #3 confirmed these were all the autoclave records available.	A 257	Whole Woman's Health of San Antonio has updated its Autoclave Load Log to include documentation of temperature and pressure of each autoclave during operation. Even though this information was not previously documented on the log, the staff sterilizing the instruments always confirmed that the autoclave was indeed reaching the required temperature and pressure to ensure decontamination and sterility of the instruments. A staff in service will be facilitated by the director of clinical services to ensure all staff understands the proper way to document the performance of each autoclave for each load. In order to monitor compliance with this requirement the clinic administrator will conduct a monthly audit of the autoclave load log and address adequate documentation and training needs.	
A 258	TAC 139.49(d)(5)(L)((ii)(VI)(VII) Infection Control Standards (L) Performance records. (ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall	A 258		11/30/15

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 10/21/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
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A 258	<p>Continued From page 19</p> <p>be maintained either manually or machine generated and shall include: (VI) results of biological tests and dates performed; and (VII) time-temperature recording charts from each sterilizer (if not provided on sterilizer recording charts).</p> <p>This Requirement Is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain performance records for the autoclave during operation that included pressures, temperatures, and times at desired temperature and pressure.</p> <p>Findings include:</p> <p>Observation on 10/20/2015 at 10:15 AM revealed a designated "Pathology" room with one (1) Pelton Delta Q autoclave.</p> <p>An Interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclaves.</p> <p>A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the time, duration and temperature of exposure phase during the operational phase of the autoclave.</p> <p>An interview with Staff #3 on 10/20/2015 at 10:45 AM confirmed there were no recordings of the time-temperature from the autoclave.</p>	A 258	<p>A 258</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are strictly followed. Whole Woman's Health of San Antonio has updated its Autoclave Load Log to include documentation of temperature and pressure of each autoclave during operation. Even though this information was not previously documented on the log, the staff sterilizing the instruments always confirmed that the autoclave was indeed reaching the required temperature and pressure to ensure decontamination and sterility of the instruments.</p> <p>A staff in service will be facilitated by the director of clinical services to ensure all staff understands the proper way to document the performance of each autoclave for each load.</p> <p>In order to monitor compliance with this requirement the clinic administrator will conduct a monthly audit of the autoclave load log and address adequate documentation.</p>	11/30/15

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 10/21/2015
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A 259	Continued From page 20	A 259		
A 259	<p>TAC 139.49(d)(5)(M) Infection Control Standards</p> <p>(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review to the facility within two hours of request by the department.</p> <p>This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to maintain preventive maintenance records for the autoclave.</p> <p>Findings include:</p> <p>Observation on 10/20/2015 at 10:15 AM revealed a designated " Pathology" room with one (1) Pelton Delta Q autoclave.</p> <p>An interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclaves.</p> <p>A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the time, duration and temperature of exposure phase during the operational phase of the autoclave.</p>	A 259		11/30/15

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A 259	Continued From page 21 An interview with Staff #3 on 10/20/2015 at 10:45 AM confirmed there were no recordings of the time-temperature from the autoclave.	A 259			

Exhibit 7.2
Legal Opinion to ISDH

PRINTED: 12/02/2015
FORM APPROVED

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008038	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 000	<p>TAC 139 Initial Comments</p> <p>Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p> <p>An entrance conference was held with the facility clinical coordinator and another facility staff member on the morning of 11/10/15. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.</p> <p>Continued licensure is recommended, with an approved plan of correction.</p> <p>An exit conference was held with the facility clinical coordinator and another administrative staff on the evening of 11/10/15. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p>	A 000	<p><i>Accepted 1/8/16</i></p>	
A 126	<p>TAC 139.41(a) Policy Development and Review</p> <p>(a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following:</p>	A 126	<p>A126</p> <p>The Clinic Administrator will be responsible for the conduct of the facility, and for the implementation, enforcement and monitoring of the written policies governing the facility.</p> <p>The clinic Administrator has placed a purchase order for small red biohazard bags, as well as small biohazard stickers as a backup option for storing pathological waste in the biohazard freezer.</p>	12/28/15

SOD - State Form
LABORATORY

STATE FORM

SIGNATURE

TITLE

(X6) DATE

LVP, Clinic Administrator

01/06/2016

8008

RNHO11

If continuation sheet 1 of 7

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008038	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
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A 126	Continued From page 1 This Requirement is not met as evidenced by: Based on a review of policies, tour of the facility, and interview the facility failed to enforce written policies governing the facility's total operation, to provide health care in a safe and professionally acceptable environment. Findings included: Facility procedure entitled, "Procedure for pathology" stated in part, "10. The staff member will dispose of the POC into a small biohazard bag. When that bag is full or at the end of a session (whichever comes first), the staff member will place that bag into another Ziploc and put it into the path lab freezer." During a tour of the facility on 11/10/15 it was observed that the freezer that the biohazard Ziploc bags containing POC (products of conception). The POC was not in a labeled biohazard bag. In an interview on 11/10/15, staff member #2 confirmed that all POC should be placed in a biohazard bag prior to being placed in a Ziploc bag and stored in the designated freezer.	A 126	An In Service will be facilitated to reiterate to staff that when working pathology, the POC should be placed in a small red biohazard bag to be stored in the freezer, even though all the small bags will be placed in a large biohazard bag and container to be transported out of the building. In the event the clinic has to use zip lock bags, a biohazard sticker will be placed on the outside of the bag in order to properly identify the bag before placing it inside the biohazard freezer. In order to monitor compliance with this requirement, the clinic administrator will conduct randomized tracers on staff working in the pathology lab, findings will be discussed during the quality assurance meetings.	01/04/15
A 197	TAC 139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows.	A 197	The Clinic Administrator will be responsible for ensuring all physical and environmental requirements are accurately followed.	

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 197	<p>Continued From page 2</p> <p>(1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;</p> <p>This Requirement is not met as evidenced by: Based on observation and an interview with staff, the facility failed to have a safe and sanitary environment that was maintained to protect the health and safety of patients and staff at all times.</p> <p>Findings were:</p> <p>During a tour of the facility on 11-10-15, the following observations were made:</p> <ul style="list-style-type: none"> - The vinyl cover on the exam table in the sonograph room contained tears, which can harbor bacteria and prevent the exam table from being completely cleaned. - Examination of the medications in the emergency cart revealed 2 vials of Calcium Gluconate 10 % injectable 10 ml with an expiration date of 10/15, 1 bag of Lactated Ringers 500 ml IV with an expiration date of 5/2015, 1 ET Tube with brown discoloration/staining visible on the packaging, and 1 suction tubing with a torn/open packaging. The expired medications and damaged supplies were available for patient use. <p>The above was confirmed in an interview, with staff #2 during a tour of the facility on 11-10-15.</p>	A 197	<p>The creases on the vinyl cover on the exam table in the sonogram room will be repaired. This exam table won't be in use until the creases have been fixed.</p> <p>Due to a clerical error expired medications were kept with current medications in the crash cart, those have now been removed and properly discarded. Staff has received training on how to evaluate the need to replace medical supplies that do not have expiration dates, the ET and suction tubing have been removed from the cart, and have been replaced by new ones.</p> <p>In order to ensure compliance with the physical and environmental requirements mandated by the state, the clinic administrator will conduct a physical walk through of the facility to inspect the appearance and functionality of all equipment. Findings will be addressed during the quality assurance meetings.</p>	

Texas Department of State Health Services

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
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A 201	Continued From page 3	A 201		
A 201	<p>TAC 139.48(1)(E)(F) Physical & Environmental Requirements</p> <p>The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (E) store hazardous cleaning solutions and compounds in a secure manner and label substances; (F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of §§229.161 - 229.171 of this title (relating to Texas Food Establishments);</p> <p>This Requirement is not met as evidenced by: Based on a tour of the facility, the facility failed to store hazardous cleaning solutions and compounds in a secure manner. Failure to do so increases the risk of harm to patients.</p> <p>Findings were:</p> <p>During a tour of the facility on 11-10-15, the unlocked laundry room contained items including disinfectant spray, air freshener spray, germicidal wipes, all-purpose spray cleaner and bleach.</p> <p>The above was confirmed in an interview, with staff #2 on 11-10-15 during a tour of the facility.</p>	A 201	<p>A201</p> <p>The Clinic administrator will be responsible for ensuring the physical and environmental requirements for the facility are followed accurately.</p> <p>The Clinic will install locks on the laundry closet cabinets, and ensure all cleaning products are locked during patient care hours.</p> <p>A staff in service will be facilitated on 01-15-16 to ensure all staff is aware of ensuring these products are to be locked during patient care.</p> <p>The clinic Administrator will ensure compliance with this requirement by conducting random walk through of the facility. Findings will be addressed during quality assurance meetings.</p>	01/15/16
A 249	<p>TAC 139.49(d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards</p> <p>J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall</p>	A 249		

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 249	<p>Continued From page 4</p> <p>ensure proper storage and handling of items in a manner that does not compromise the packaging of the product.</p> <p>(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage.</p> <p>(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.</p> <p>(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.</p> <p>(iv) Storage of supplies shall be in areas that are designated for storage.</p> <p>This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to store peel pouches in a position that was free of being crushed, bent, compressed, or punctured.</p> <p>FINDINGS:</p> <p>During a tour of the facility on 11/10/15, multiple peel pouches were observed stored on a counter in the pathology room. Approximately 10 peel packs were crushed and compressed, the adhesive seal across the bottom of these peel packs was observed to be wrinkled with small gaps present, presenting a risk for contamination. The tacking of the packs also presented a risk of the packaging being punctured.</p> <p>An interview with Staff #3 on 11/10/15, confirmed the above findings.</p>	A 249	<p>A249</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed.</p> <p>The Clinic Administrator along with the staff trained to work in the pathology and sterilization lab, will reorganize the area and designate storage space on the clean side cabinets to carefully stack sterilized pouches in a position free of being crushed, bent, compressed or punctured.</p> <p>In addition a staff in service will be facilitated to ensure staff understands how to properly store packs and pouches.</p> <p>In order to monitor compliance with this requirement, the Clinic Administrator will conduct random weekly inspections of the sterilized stored instruments. Findings will be addressed during quality assurance meetings.</p>	01/15/16

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008036	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 356	Continued From page 5	A 356		
A 356	<p>TAC 139.56(b)(c) Emergency Services</p> <p>(b) The facility shall have the necessary equipment and personnel for cardiopulmonary resuscitation as described in §139.59 of this title (relating to Anesthesia Services).</p> <p>(c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities.</p> <p>This Requirement is not met as evidenced by: Based on a review of personnel files and an interview with staff, the facility failed to ensure that all direct care personnel were competent in and maintained current certification in cardiopulmonary resuscitation (CPR), as there was no documented evidence of hands-on skills practice and in-person assessment and demonstration of CPR skills. This presents a risk, as staff may not be competent to respond in a medical emergency.</p> <p>Findings Included:</p> <p>A review of personnel files revealed that 3 of 6 direct staff members at facility (#1, 2, and 4) obtained cardiopulmonary resuscitation (CPR) through an online resource that contained no evidence of hands-on skills practice, an in-person assessment and/or demonstration of CPR skills. In an interview, on 11/10/15, staff member #2 confirmed that the online course did not contain hands-on skills practice, an in-person assessment and/or demonstration of CPR skills.</p>	A 356	<p>A356</p> <p>The Clinic Administrator will be responsible for ensuring all personnel complies with emergency services requirements.</p> <p>All staff members will receive Cardiopulmonary resuscitation (CPR) training by January 4, 2016.</p> <p>Documented evidence of hands on skills practice and in person assessment will be placed in personnel files. The Clinic Administrator will ensure compliance with this requirement by conducting monthly audits of the personnel files, and scheduling the proper recertification as needed.</p>	01/04/16

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008036	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 11/10/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP			STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
A 356	Continued From page 6 Review of the Health & Safety Institute and the National Safety Council website found at http://news.hsi.com/onlineonlycpr reveals that, "No major nationally recognized training program in the United States endorses certification without practice and evaluation of hands-on skills. According to the Occupational Safety and Health Administration (OSHA) online training alone does not meet OSHA first aid and CPR training requirements."	A 356			

You are here: Home / Press Releases / Over \$83,000 in Fines Assessed in Texas for Illegal Dumping of Aborted Baby Remains



Over \$83,000 in Fines Assessed in Texas for Illegal Dumping of Aborted Baby Remains

December 1, 2011 By Operation Rescue 3 Comments

Austin Texas – The Texas Commission on Environment Quality has released documents to Operation Rescue that show two Texas abortion clinics and the disposal company Stericycle have been slapped with fines in excess of \$83,000 for illegal dumping of aborted baby remains.

The fines are the result of complaints filed by Operation Rescue against Whole Woman's Health of McAllen and Austin after a three-month undercover investigation. The TCEQ then conducted its own investigation and broadened the case to include Stericycle. In June, the TCEQ notified Operation Rescue that the two abortion clinics and Stericycle had all been cited for violations involving the improper disposal of human fetuses.

Fines for the violations were finalized three months later. TCEQ also ordered the abortion clinics and Stericycle to make specific changes in their operations.

The two abortion clinics also received a deferral of twenty percent of their fines on the same compliance contingency. However, if the TCEQ finds that they are not satisfactorily complying with the order, they will be required to pay the full amount.

"Our investigation only scratched the surface of what is really going on at abortion clinics in Texas. These hefty fines totally over \$83,000 show that the violations we discovered were valid and serious," said Operation Rescue President Troy Newman. "We can only imagine what

- Whole Woman's Health of McAllen was fined at total of \$17,430. It is required to make monthly payments of \$385.
- Whole Woman's Health of Austin was ordered to pay a total of \$22,980. It must pay off its fine with \$510 payments each month.
- Stericycle received the largest fine of \$42,612, which was paid in one lump sum minus twenty percent, which is deferred contingent upon satisfactory future compliance.

the public's welfare." In addition to the TCEQ fines, ten abortionists must answer to the Texas Medical Board for other abortion abuses discovered by Operation Rescue. Word on the extent of their discipline is expected in February.



Dumpsters behind Whole Woman's Health were open and spilling trash. Infectious waste and other hazardous materials, and private medical records were illegally dumped there.

would be found if every abortion clinic was thoroughly investigated."

"Abortion clinics cannot be trusted to follow the law or tell the truth about it even if they are caught," said Newman. "Time and again we have seen that abortionists have the attitude that they are above the law. Abortion clinics need to be inspected and violations strictly enforced for the sake of

(<http://dailycaller.com/>)



EXHIBIT 9
Legal Opinion to ISDH

HEALTH

(<http://dailycallernewsfoundation.org/>)

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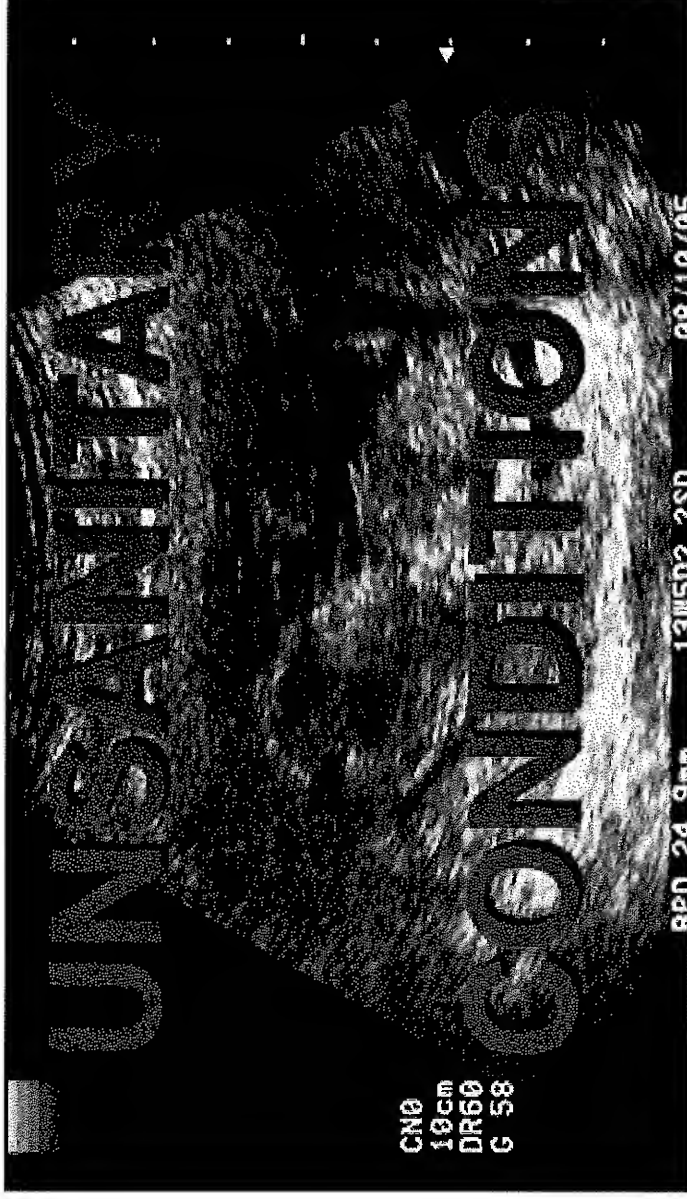
Abortion Clinics Are Crawling With Dirty Health Violations, Report Finds

by GRACE CARR, reporter

(<http://dailycaller.com/author/grace-carr/>)

11:57 AM 10/27/2017





A string of abortion clinics across the country continues to violate the law and jeopardize the health and lives of women by failing to keep clinics clean and train staff adequately, according to the Texas Department of State Health Services.

A slew of Whole Woman's Health (WWH) abortion clinics miserably failed inspection reports between 2011 and 2017, [the Free Beacon reported \(http://freebeacon.com/issues/texas-abortion-clinics-marred-health-safety-issues-inspection-reveals/?utm_source=Freedom+Mail&utm_campaign=eb64ddce41-EMAIL_CAMPAIGN_2017_10_26&utm_medium=email&utm_term=0_b5e6e0e9ea-eb64ddce41-46249161\)](http://freebeacon.com/issues/texas-abortion-clinics-marred-health-safety-issues-inspection-reveals/?utm_source=Freedom+Mail&utm_campaign=eb64ddce41-EMAIL_CAMPAIGN_2017_10_26&utm_medium=email&utm_term=0_b5e6e0e9ea-eb64ddce41-46249161) in conjunction with the nonprofit And Then There Were None (ATTWN).

"Anyone who cares for women's health and safety should want abortion facilities to be frequently inspected, no matter what their position is on abortion. Because this is a health and safety issue, and just because it has to do with a hot button topic, does not mean that the abortion industry should get a free pass," Arina Grossu, Center for Human Dignity ^

Director at the Family Research Council, told the Free Beacon. “Restaurants and tanning salons and vet clinics, they’re all more closely regulated than the abortion industry.”

Medical instruments were unsterile and rusty, medication had expired, staff were inadequately trained, and the facilities were dirty enough to constitute health hazards, the inspection reports found. The inspections also discovered faulty patient records, disregard for informed consent, undercover calls and visits from minors, and waiting period violations. The Beaumont, Texas WWH clinic did not even have a registered nurse on staff in 2011.

A WWH abortion clinic in McAllen, Texas was in disrepair, with stains, cracks in exam tables and holes in the flooring, a 2016 study found. ATTWN’s 2017 report also found missing stocks of fentanyl, which has responsibility for the rise of thousands of deaths in the ongoing opioid crisis. **(RELATED: Opioid Crisis: A Daily Game Of Russian Roulette)** (<http://dailycaller.com/2017/09/29/opioid-crisis-a-daily-game-of-russian-roulette/>).

“I was appalled at the state of the Austin Whole Woman’s Health. It looked more like a prison than an actual facility where patients went for healthcare. Disgusting does not do it justice,” ATTWN founder Abby Johnson said. The WWH clinic in Austin even had blood on the walls, she noted.

“What we see in the abortion industry across the country is that inspections are done, people come in, they’re cited for violations, they make a temporary plan to improve, a year later an inspector comes in, they cite them for the same violations, they make a temporary plan to improve ... it’s the same cycle, over and over again,” she said. “If we’re going to say that we’re for women, and we’re for protecting women, then this was sort of a common sense measure.”

More than 220 abortion clinics between 2008 and 2016 — including six (<http://unsafe.aul.org/wp-content/uploads/2016/12/Unsafe-Chart.pdf>) WWH clinics — were cited for 1,400 health and safety violations, according to a 2016 Americans United For Life (AUL) report (<http://www.lifeissues.org/wp-content/uploads/2017/01/UNSAFEreport.pdf>).


WWH was also involved in a lengthy lawsuit, *Whole Woman’s Health v. Hellerstedt* (<http://www.scotusblog.com/case-files/cases/whole-womans-health-v-cole/>), regarding restrictions on abortion services.



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Why Should Abortionists Have Admitting Privileges? Look at These Botched Abortions at Just One Clinic

STATE (HTTP://WWW.LIFENEWS.COM/CATEGORY/STATENEWS/)

CHERYL SULLINGER MAY 19, 2014 | 11:53AM AUSTIN, TX



Whole Women's Health of Austin where documents show a string of abortion-related medical emergencies.

After the passage in Texas last summer of an historic pro-life law known as HB2, hardly a week as gone by without articles penned by abortion supporters lamenting the new regulations as nothing more than a ploy to shut down abortion clinics.

Amy Hagstrom-Miller, President of the Whole Women's Health abortion clinic chain, is perhaps one of the loudest voices condemning the new law that has already closed 20 Texas abortion clinics — including two of hers. Once the rest of the provisions take effect this September, it is likely that only six abortion clinics will remain in the Lone Star State.

(<http://lifefews.wpengine.netdna-cdn.com/wp-content/uploads/2014/05/wholewomens.jpg>) Causing particular angst has been the requirement that abortionists maintain hospital privileges within 30 miles of their clinics.

“Our elected officials lied to all of us, HB2 has nothing to do with improving women’s health and safety; but rather it is a proven and successful strategy to end safe abortion care for women in Texas,” opined Hagstrom-Miller just last month.

However, Operation Rescue has received three 911 records from just one of Hagstrom-Miller’s abortion clinics, Whole Women’s Health of Austin, over a 30-day period in 2012 that shows the clinic has a poor track record when it comes to women’s safety.

“This documentation loudly refutes Ms. Hagstrom-Miller’s fantasy that the hospital privilege requirement and other safety regulations in the Texas law have nothing to do with patient safety. In fact, if patient safety was more of a concern to abortion clinics, perhaps we wouldn’t see the long line of women being transported to the hospital, and in some cases, the morgue,” said Troy Newman, President of Operation Rescue.

The following incidents were documented through 911 Computer Aided Dispatch Transcripts obtained by Operation Rescue:

- March 17, 2012: A 20-year old female patient was transported to Saint David’s Hospital suffering from an allergic reaction. This incident was of moderate severity, but required emergency hospital intervention.
- April 2, 2012: A 34-year old female was rushed to North Austin Hospital with a priority designation that indicated her condition was life-threatening. In fact, paramedics responding to the call upgraded the patient’s priority upon assessment of her condition. The WWH caller told dispatchers that the woman was breathing and conscious, but not alert. She was suffering abdominal pain and vomiting while at the clinic. This was the lost serious of the three incidents.
- April 18, 2012: A sick and vomiting 22-year old female patient was transported to St. David’s Hospital. Records indicate that she suffered “no priority symptoms,” nevertheless, she required emergency hospital treatment that could not be provided at WWH.

This 30-day snapshot of emergencies at just one Whole Women’s Health abortion clinic shows that the these facilities are not equipped to handle even the least serious of complications that can be expected to occur at abortion clinics, much less the life-threatening ones.



Whole Women’s Health of Austin where documents show a string of abortion-related medical emergencies.

When emergencies occur, it is imperative that there is continuity of patient care so that emergency treatment is not delayed, especially in life-threatening situations, such as was inflicted upon the 34-year old patient on April 2, 2012. Even a short delay while hospital physicians struggle to diagnose a patient's condition, as we saw in the case of Tonya Reaves (<http://www.operationrescue.org/archives/planned-parenthood-abortionist-evaded-blame-shifted-in-death-of-tonya-reaves-deposition-shows/>), who died at a Chicago, Illinois Planned Parenthood clinic in 2013 can mean the difference between life and death. The hospital privilege requirement adds a layer of protection for women who suffer abortion complications from suffering a delay in care.

Despite Ms. Hagstrom-Miller's hysteria, the Texas law — particularly the local hospital privilege requirement — is all about patient safety. Given the frequency with which Whole Women's Health sends patients to the hospital emergency rooms for medical help the clinics cannot provide, these laws are critically needed to ensure that women get the care they need.

If the law results in the closure of abortion clinics that cannot guarantee patient safety or continuity of care in the event of a medical emergency, then it is in the best interests of women for those abortion clinics to close. Hagstrom-Miller's attitude only reveals that the health and safety of women take a back seat to her financial profit margin, which is currently enhanced by cutting corners on women's lives.

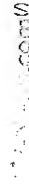
View March 17, 2012 CAD transcript (<http://operationrescue.org/pdfs/CAD-WWHAustin-03172012.pdf>)

View April 2, 2012 CAD transcript (<http://operationrescue.org/pdfs/CAD-WWHAustin-04022014.pdf>)

View April 18, 2012 CAD transcript (<http://operationrescue.org/pdfs/CAD-WWHAustin-04182012.pdf>)

LifeNews.com Note: Cheryl Sullenger is a leader of Operation Rescue (<http://www.OperationRescue.org>), a Kansas-based pro-life that monitors abortion practitioners and exposes their illegal and unethical practices. The group is known for serving as a watchdog of Planned Parenthood and other abortion businesses.

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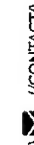
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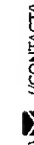
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State	City	Abortion Provider	Incident(s) Description	Documentation/Resources
IL	Peoria	National Health Care Services (now named Whole Women's Health of Peoria)	<p>The Illinois Department of Public Health noted on July 6, 2011 that deficiencies and violations at National Health Care Services included:</p> <ul style="list-style-type: none"> - Staff not adequately trained was performing duties they should not have the potential for cross contamination of contagions. - Water temperature was not hot enough. - Snack nuts and packages of cookies were on the crash cart. - Failure to ensure staff training for emergency or non-emergency situations were conducted. - Facility failed to ensure medical histories and complete physical examinations were reviewed by the physician prior to the procedure. - Facility failed to ensure personnel administering intravenous sedation was qualified in the State of IL to administer anesthesia, <p>RNs administering moderate sedation had multiple clinical responsibilities, were not ACLS certified and the physicians were not privileged to administer moderate sedation. No documentation to indicate physicians were ACLS certified.</p>	<p>EXHIBIT 11 Legal Opinion to ISDH</p> <p>IL Department of Public Health Division of Health Facilities Standards: Statement of Deficiencies and Plan of Correction. Date of Survey: July 6,</p>

MD	Baltimore	Whole Women's Health Baltimore	<p>The Statement of Deficiencies Report from the February 22, 2013 inspection of Whole Women's Health Baltimore found deficiencies included:</p> <ul style="list-style-type: none"> ■ Failure to secure the medical waste sharps container and protect the safety of patients. ■ Failure to implement their policy and procedures for the use and storage of medications. 	<p>Maryland Department of Health and Mental Hygiene, Statement of Deficiencies and Plan of Correction, Whole Women's Health Baltimore, Inspection Date February 22, 2013, <i>available at</i> http://abortiondocs.org/wpcontent/uploads/2014/11/Whole-Womens-Health-Baltimore-Initial-Survey-2-22-2013.pdf</p>
NC	Chapel Hill	Women's Health Alliance	<p>The Statement of Deficiencies Report from the April 3, 2014, inspection of Women's Health Alliance found the following deficiencies:</p> <ul style="list-style-type: none"> - Failure to have a witnessed voluntarily-signed informed consent for each surgery or procedure in 1 of 4 clinic records reviewed of patients that had abortion procedures. - Failure to verify the patient's full and true name for 4 of 4 patients who had abortion procedures. - Failure to maintain a daily procedure log of all patients receiving abortion services along with type of procedure, time of procedure, and Name of the Registered RN on duty. - Failure to ensure medications were administered by a RN or LPN in accordance with the State of NC for 2 of 2 patients who were administered medications and had a surgical abortion procedure performed. - Failure to ensure sterile instruments were not outdated and failed to ensure autoclave testing was performed per clinic policy. 	<p>North Carolina Division of Health Service Regulation, Statement of Deficiencies, Women's Health Alliance, for inspection on April 3, 2014, <i>available at</i> https://www2.ncdhs.gov/dhsr/a-hc/sods/2014/20140403-933088.pdf</p>

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Texas Abortion Clinics Marred with Health, Safety Issues, Inspection Reveals

Posted By *Charles Fain Lehman* On October 27, 2017 @ 5:00 am In Issues | [No Comments](#)

New detailed inspection reports reveal dozens of violations of health and safety standards by Whole Woman's Health (WWH), a chain of abortion clinics that says it is "committed to changing the culture around abortion stigma."

The new documents, inspection reports between 2011 and 2017 from the Texas Department of State Health Services, were obtained by And Then There Were None (ATTWN), a nonprofit group that "exists to help abortion clinic workers leave the abortion industry."

The documents show a widespread problem of health violations at WWH clinics. Staff failed to properly disinfect and sterilize equipment used on multiple women, and were not properly trained in the sterilization of surgical instruments. In 2011, the Beaumont, Texas, clinic did not have a registered nurse on staff, in contravention of legal requirements.

The inspector's reports also expressed concerns about maintenance of medical equipment. "There was [sic] numerous rusty spots on the suction machine used on the patient for evacuation of the products of conception," the Beaumont report notes. In multiple cases, supplies and medication were found to be clearly expired.

Facilities themselves were also in disrepair, with floors that were "stained and discolored which gives the appearance of being dirty." A 2016 report on the McAllen, Texas, facility notes a counter so warped it "was no longer a wipeable surface, which could harbor bacteria and infectious matter." The reports also show cracks, rips, and tears on exam tables' covers, and a hole in cabinet flooring that had "the likelihood to allow rodents to enter the facility."

In the most recent report, investigating the Austin facility, investigators found missing stock of fentanyl, the schedule narcotic linked to thousands of overdose deaths.

These reports are part of broader concerns about the safety standards of abortion clinics. According to a report from the pro-life advocacy group Americans United for Life, between 2008 and 2016, 227 abortion clinics, including six Whole Woman's Health clinics, were cited for over 1,400 health and safety deficiencies. These included failures to ensure a "safe and sanitary environment" and failures to properly handle patients' private information.

"Restaurants and tanning salons and vet clinics, they're all more closely regulated than the abortion industry," said Arina Grossu, a bioethicist and the Director of the Center for Human Dignity at the Family Research Council.

Grossu pointed out how regulators and inspectors often look the other way when investigating abortion facilities. Such was true, Grossu said, in the case of abortion doctor and convicted murderer Kermit Gosnell. Pennsylvania state regulators did not inspect Gosnell's facility, out of concerns that inspections would be "putting a barrier up to women" seeking abortions.

"Anyone who cares for women's health and safety should want abortion facilities to be frequently inspected, no matter what their position is on abortion. Because this is a health and safety issue, and just because it has to do with a hot button topic, does not mean that the abortion industry should get a free pass," Grossu told the *Free Beacon*.

Abby Johnson, ATTWN's founder, had previously toured a WWH clinic in Austin, where she documented dirty equipment and what she took to be blood on the walls.

"I was appalled at the state of the Austin Whole Woman's Health. It looked more like a prison than an actual facility where patients went for healthcare. Disgusting does not do it justice," Johnson said.

Johnson, like Grossu, sees these failed health inspections as part of the broader trend of repeated failures of oversight in the abortion industry.

"Laws only matter if they're enforced. And what we see in the abortion industry across the country is that inspections are done, people come in, they're cited for violations, they make a temporary plan to improve, a year later an inspector comes in, they cite them for the same violations, they make a temporary plan to improve ... it's the same cycle, over and over again," she said.

WWH's violations are of particular note because the group was the plaintiff in a case that went all the way to the Supreme Court in a successful effort to ensure that abortion clinics were not required to meet high medical standards.

In 2013, the Texas State Legislature passed, and then-Gov. Rick Perry (R.) signed, H.B. 2. Among other limits on abortion, the bill imposed requirements that physicians at abortion clinics have admitting privileges at a hospital within 30 miles of the clinic; that they provide a 24-hour contact number for patients to reach them at; and that abortion clinics meet the health and safety standards of ambulatory surgical centers, a particular kind of clinic that provides surgeries as an alternative to hard-to-access hospitals.

"If we're going to say that we're for women, and we're for protecting women, then this was sort of a common sense measure," Johnson said.

Johnson, who lobbied for the bill, noted that many of the Planned Parenthood centers opened in Texas since the passage of H.B. 2 met the ambulatory surgical center standards voluntarily. However, WWH decided that the health and safety requirements were unconstitutionally burdensome.

WWH brought suit, alleging that H.B. 2 violated it and its clients' constitutional rights. The state of Texas responded that it was simply trying to ensure the health and safety of its female citizens. That suit eventually came before the Supreme Court which, in a 5-3 decision, agreed with WWH.

"The Texas law called H. B. 2 inevitably will reduce the number of clinics and doctors allowed to provide abortion services.... it is beyond rational belief that H. B. 2 could genuinely protect the health of women, and certain that the law `would simply make it more difficult for them to obtain abortions,'" wrote Justice Ruth Bader Ginsburg in a brief concurrence.

Justice Samuel Alito, for his part, warned that the court's rush to support abortion rights meant that it failed to adequately investigate the surgical center requirements as anything but a "package," leading to the striking down of obvious and constitutionally sound safety measures.

"Provisions that are indisputably constitutional—for example, provisions that require facilities performing abortions to follow basic fire safety measures—are stricken from the books. There is no possible justification for this collateral damage," Alito wrote.

Article printed from Washington Free Beacon: <http://freebeacon.com>

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Charles Fain Lehman

Email: [Charles \(mailto:comments@freebeacon.com\) | Full Bio \(http://freebeacon.com/author/charles-lehman/\) | RSS \(http://freebeacon.com/author/charles-lehman/feed/\)](mailto:Charles (mailto:comments@freebeacon.com) | Full Bio (http://freebeacon.com/author/charles-lehman/) | RSS (http://freebeacon.com/author/charles-lehman/feed/))

Charles Fain Lehman is a staff writer for the Washington Free Beacon. He writes about policy, especially crime, law, drugs, and social issues. Reach him on twitter (@CharlesFLehman) or by email at lehman@freebeacon.com.

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Exhibit 7.1
Legal Opinion to ISDH

PRINTED: 12/28/2016
FORM APPROVED

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 10/21/2016
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 000	<p>TAC 139 Initial Comments</p> <p>Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p> <p>An unannounced visit was made on the morning of 10/20/2016 to conduct a Re-licensure Survey to determine compliance with 26 TAC Chapter 139 State Licensing Rules for Abortion Facility.</p> <p>An entrance conference was conducted with the Director of Clinic Services. The purpose of the visit and procedure for the survey was discussed.</p> <p>An exit conference was conducted on 10/21/16 with the Director of Clinic Services. Deficiencies were cited. The facility's personnel was given an opportunity to provide additional information and ask questions.</p>	A 000	Accepted 11/5/16	
A 149	<p>TAC 139.44(b)(3)(A)(B)(C)(D) Orientation/Training/Demonstrated Competency</p> <p>(3) the employee understands, at a minimum but not limited to, the following: (A) coordination and treatment of patient care; (B) sterilization and infection control policies; (C) patient education/information; (D) informed consent policies;</p>	A 149	<p>A149</p> <p>The Clinic Administrator will be responsible for ensuring all personnel working in the pathology lab has gone through the appropriate orientation process, training and demonstrate competency on decontamination and sterilization techniques.</p>	11/30/16

SOD - State Form
LABOR

STATE

IDENTATIVE'S SIGNATURE

TITLE

(X5) DATE

Director of Clinical Services
JME311

11/5/16 12/08/16

If continuation sheet 1 of 22

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A 149	<p>Continued From page 1</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure 1 (#3) of 1 was trained in the sterilization process of surgical instruments.</p> <p>Observed during the tour on 10/20/2015 at 10:15 AM there were approximately 20 sterile instruments packaged in peel pouches which were being stored in a plastic container with no lid. These instruments were stored in the room where products of conception were examined and contaminated instruments were washed. The peel pouches were observed to have water stains or discoloration noted on the sterile packages. There were no chemical indicators inside the peel pouches. Also, observed the peel pouches were not sealed correctly. There is a perforated line where the pouches are to be folded. The pouches were not folded correctly which allowed outside contaminated air to enter the pouches. The peel pouches were observed to be crushed, bent, and compressed in the plastic container, which had no lid and the container was over filled with instruments. The peel packs were not labeled with the load number, date and or time. A review of the of the steam sterilizer operation guide recommends no more than 1.8 lbs., if using the appropriate tray and pouches may not be stacked. It was observed in the sterilizer a load with peel pouches and 4 wrapped instrument sets on the day of tour. There was no tray in the sterilizer to separate the instruments. The instruments were lying on top of each other which allowed no room for the instruments to have air circulation for proper sterilization and drying.</p>	A 149	<p>During the survey conducted on 10/21/15 the surveyor noted staff was not properly sealing the sterilization pouches, therefore according to the surveyor allowing contaminated air to get inside the pouch. There is no indication of infection control hazard to patients due to the air circulating throughout the facility, Whole Woman's Health of San Antonio has not reported an increase of infection rate.</p> <p>The Director of Clinical services will facilitate an infection control training on November 30th, 2015. Staff will be required to prepare for this training by reading WWH policy for decontamination and sterilization techniques, during the training the designated trainer will show the staff the proper way to wrap, pack and sterilize instruments, by the end of the training the staff will be asked to perform each one of these steps while being evaluated by the trainer. A competency checklist will be documented and filed in the staff's personnel record.</p> <p>In order to ensure compliance, the Clinic Administrator will perform randomized tracers to address staff's competency and follow through of our policies and address training needs.</p>	

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A 149	<p>Continued From page 2</p> <p>A review of the autoclave load log from 9/29/2015 thru 10/19/2015 revealed no temperature, time, or pressure recorded on the log.</p> <p>A review of the record titled, "Whole Women's Health Pathology Training Checklist" revealed the only record of training for Staff #3. There was no training on sterilization of sterile instruments.</p> <p>Review of the policy titled, "Procedure Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" revealed the following:</p> <p>"Maintenance of Sterility Items that are packaged properly will remain sterile unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of being compromised. Commercially packaged items will be considered sterile according to the manufacturer's instructions. A. All packages will be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item will be returned to the sterile area for reprocessing/sterilizing. B. The indicator tape on the outside and on the inside of the pack will be checked before the instruments are used. If the indicator tape did not change the pack will be returned to the sterile area for reprocessing/sterilizing. The other packs/pouches from that load will be checked. C. If instruments are ("flash") sterilized unwrapped an indicator tape or strip will be placed in the tray and presented to the providing MD along with the instrument. D. Sterilized items will be handled in a manner that does not compromise the packaging of the product.</p>	A 149		

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A 149	Continued From page 3 E. Sterilized Items will be transported as to maintain cleanliness and sterility and to prevent physical damage. F. Sterilized Items will be stored in the sterile area. This area has controlled ventilation and has restricted access. G. Sterilized Items will be packed in the sterilizers and positioned so the packaging is not crushed, bent, compressed, or punctured in order to ensure the packages' sterility." An interview with Staff #3 on 10/20/2015 at approximately 3:00 PM confirmed the above findings and the policy was not being followed. Staff #3 was asked what type of training have you had on the sterilization of instruments. Staff #3 stated, "I just shadowed someone for couple of days." The interview with Staff #3 revealed the staff member was still not knowledgeable in the proper procedure of sterilizing instruments.	A 149			
A 197	TAC 139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times; This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to provide safe and sanitary environment.	A 197	A197 The Clinic Administrator will be responsible for ensuring the physical and environmental requirements for the facility are strictly followed.	11/30/15	

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A 197	Continued From page 4 During the tour of the facility on 10/21/2015 at approximately 10:00 AM the following environmental issues were observed: The findings included: Laboratory Area: Patient lab supplies were being stored under the sink in the Lab room. Observed a brown substance on patients' supplies and on the floor of the sink shelf which appeared to be a leak. Pathology Room: Observed some type of soap being stored in the bag out of the original container on the pathology sink. There was water on the cabinet surface where instruments are placed to dry. The Administrator laid her phone down on the cabinet in the water during the tour and stated "Oh that's wet." In the Pathology room beside the Biohazard container in a card board box sitting on the floor was the blue wrap for the surgical instruments. In the pathology room (what the facility calls the sterile side) was another box of the blue wrap in a card board box sitting on the floor. The products of conception were being examined and contaminated instruments were being washed in this same room. The width of area discussed was approximately 3 feet that separated clean from dirty. A fan was sitting on top of the surgical trays on the shelf, the under the cabinet in the Pathology room. In the Pathology room 15 gallons of Cidex, Enzymatic solution, and bleach were being stored	A 197	Laboratory Area: All patient supplies have been removed from the cabinet under the sink, and have been stored in a plastic container on a separate cabinet. The packaging that was stained with betadine "brown substance" has been removed from the lab and properly disposed. An infection control training outlining the proper method to store laboratory supplies was facilitated for staff on 11/11/15, and the records have been failed in the each staff's personnel record. Recovery Room: The oxygen tank has been moved to a safer place away from risk of being knocked down by patients, visitors, or staff. Laundry Room: The Laundry room has been re organized with the intent of maintaining a clear separation between the dirty linens, and the clean laundry. All janitorial supplies have been properly stored in a closet designated for janitorial supplies. Physical walk through of the facility: The exam tables, and suction machines will be refurbished to address the peeling paint, and the ceiling tile with the 3 inch water mark in the lab will be replaced.	11/11/15	11/11/15
				11/12/15	
				11/30/15	

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A 197	<p>Continued From page 5 directly on the floor.</p> <p>Patient Storage Closet:</p> <p>In the patient care closet, where patient supplies are stored it was observed there were sanitary pads on the floor. Dust particles were on the floor next to the sanitary pads along with a biohazard sharps container and card board boxes. The patient supplies were open on the shelves, and it was observed that there were card board shipping boxes on the shelves beside the open patient supplies. Also, there were card board shipping boxes stored on top of the open patient supplies. Card board boxes can harbor parasites, insects, and microorganisms. "External shipping containers have been exposed to unknown and potentially high microbial contamination. Also, shipping cartons, especially those made of corrugated material; serve as generators of and reservoirs for dust." (AAM1 ST46-Section 5.2 Receiving items).</p> <p>Recovery Room:</p> <p>During the tour of the recovery room on 10/20/2015 at 3:00 PM observed 2 card board shipping boxes on the floor of the recovery room. The boxes were full of patients' supplies (blue pads). The lid was open to the boxes making it available for contaminants to enter the boxes.</p> <p>There was an oxygen tank sitting on the floor in the recovery area with a holder. The oxygen tank was beside the water fountain, which made it accessible to be knocked over by staff, patients, and family members.</p> <p>An interview with Staff #1 on 10/20/2015 at 3:00 PM confirmed the above findings.</p>	A 197	<p>In order to monitor compliance with the physical an environmental requirements for the facility, the Administrator will perform a walk-through of the physical plant on a weekly basis to ensure all supplies are properly stored, ad equipment and instruments are in optimum condition.</p>	

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A 197	<p>Continued From page 6</p> <p>Laundry Room:</p> <p>During a tour of the facility on 10/20/15 and 10/21/15 of the survey card board shipping boxes were stored in front of the (2) soiled linen hampers on the floor in the laundry area. There were 4 boxes which contained paper towels and bathroom tissue stacked in front of the soiled linen hamper, and the washer and dryer. In this same area across from the soiled linen cart (approximately 3 feet) was an open wire rack where patient gowns, physicians' scrubs, and patient blankets were being stored. There were no barriers on the bottom shelf and no cover over the shelving. On the shelf with the clothing items was an autoclave. Above the patient gowns, physicians' scrubs, and patient blankets were package of paper towel rolls. There was clothing articles piled on top of the dryer along with boxes of fabric softener. Beside the dryer was another soiled linen hamper that had a shipping box on top of the linen hamper. Observed that all 3 linen hampers had soiled linen in them. The linen hampers were all labeled with biohazard label. This laundry area stayed cluttered with shipping boxes and observed that none of the staff members had ever moved or cleaned the area during the 2 day survey.</p> <p>An interview with Staff #1 on 10/21/2015 at approximately 12:00 PM confirmed the above findings. Staff #1 stated, "The boxes are here because we just got supplies."</p> <p>Observed no change in the laundry area during the survey dates of 10/20-21/2015.</p> <p>Tour of the facility on 10/20/15, the following observations were made:</p> <p>-Through out the facility, base boards were lifting</p>	A 197			

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A 197	Continued From page 7 at some of the seams and "yellowing dirt" was observed along the base of the baseboards. - In the recovery room, the exam table had rust around each drawer and around the drawer handles. - In the procedure room- Amella: the drawers of the exam table had rust and peeling paint. -In the procedure room -Georgia: The emesis basins, used for patients, were stored under the sink. The suction machine, the bumper around the machine had fallen off the machine and was covered in dust. In the Lab room: A ceiling tile had water damage. -The crash cart in the hallway of the facility was covered in dust. Interview on 10/20/15 with the staff S#1, confirmed the above findings.	A 197			
A 213	TAC 139.49(b)(1)(A)(i)(ii) Infection Control Standards (A) An abortion facility shall ensure that all staff comply with universal/standard precautions as defined in this paragraph. (i) Universal/standard precautions includes procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments. (ii) Universal/standard precautions synthesize the major points of universal precautions with the points of body substance precautions and apply them to all patients receiving care in facilities,	A 213	A213 The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed. Whole Woman's Health of San Antonio has developed a performance record for the usage of Manual Vacuum Aspirator (MVA) in order to track the usage and performance of the MVA's in rotation. (See log attached)	11/30/15	

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A 213	<p>Continued From page 8</p> <p>regardless of their diagnosis or presumed infection status.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain performance records for the usage of the Manual Vacuum Aspiration (handheld syringe used for manual evacuation for an abortion). Also, the facility failed to follow their own policy processing the Ipas MVA Plus.</p> <p>A review of records revealed no documentation that the facility was keeping records of how many times the MVA had been used.</p> <p>A review of the manufactures' guideline on the Ipas MVA revealed the following: "Providers can choose the disinfectant/sterilization method that best results their practice. As a guideline, the Ipas MVA Plus can be used between 25-50 times when following the Ipas processing instructions provided in its package insert. Whichever method of disinfection/sterilization is chosen, the Ipas MVA needs to be inspected before next use. If the Ipas MVA plus shows signs of damage or is not functioning properly, it should be discarded." During a tour of the facility on 10/20/2015 at 10:50 AM observed multiple MVA's on the counter at the nursing station in an open container with no lid. Also, observed a MVA lying on the second shelf of a rolling cart. The MVA was lying on an open surface with no cover over the MVA. The cart was used to carry supplies in and out of the procedure room. A review of the facility policy titled, "Procedure Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" revealed the</p>	A 213	<p>The medical director will conduct an inspection of all MVA's in rotation to assess their current condition and need for replacement. This audit will be documented and kept in the performance record binder. All MVA's devices will be stored in a closed plastic container before use.</p> <p>A staff training will be provided by the Director of Clinical Services to ensure the staff understand the process to decontaminate and sterilize these devices, as well as the steps to inspect them before use and document the number of times it is used.</p> <p>In order to ensure compliance with this requirement, the Clinic Administrator will conduct a monthly audit of the performance record log as well as the condition of the MVA's.</p>	

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A 213	Continued From page 9 following: "Cleaning and Processing the Ipas MVA Plus: *Clean it by washing all surfaces thoroughly in warm water and detergent. Detergent is preferable to soap, which can leave a residue. As an alternative, an enzymatic cleaner, a solution specifically designed to clean blood and tissue from surgical instruments, can be used. *For a high-level disinfectant soak, place all the parts in the soak for the amount of time directed on the bottle. Ipas recommends Cidex or Cidex OPA, or Sporox II, however, Cidex OPA is the Facility's approved disinfectant soak. Ipas MVAs must soak in Cidex OPA for at least 12 minutes. *The Ipas MVA Plus can be used between 25 and 50 times when following the Ipas processing instructions. The Ipas MVA should always be inspected before next use, and should be discarded at any signs of damage or is not functioning properly. *Aspirators need to be stored in dry, covered containers or packages to protect them from dust and other contaminants." An Interview with Staff #1 on 10/21/2015 at 10:30 AM confirmed the facility was not keeping a record of how many times the MVA had been used.	A 213		
A 242	TAC 139.49(d)(5)(D)(i)(ii) Infection Control Standards D) Packaging. (i) All wrapped articles to be sterilized shall be	A 242	A242 The Clinic Administrator will be responsible for ensuring all infection control standards are being followed by ensuring the sterilization procedure is strictly monitored.	10/22/15 11/30/15

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A 242	<p>Continued From page 10</p> <p>packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs shall be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays shall not exceed 17 pounds.</p> <p>(ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to document on the instrument packages the following: the date and time of sterilizing, sterilizing load number, and the identification of the autoclave used.</p> <p>Observed during the tour of the sterilization room on 10/20/2015 at approximately 10:14 AM the peel pouches in the plastic container and the peel pouches that were being removed from the autoclave were not labeled with date and time sterilized, sterilizing load number, and the identification of the autoclave used. The wrapped instruments that were removed from the autoclave were not labeled with date and time sterilized, sterilizing load number, and the identification of the autoclave used.</p> <p>An interview with the Staff #3 on 10/20/2015 at 11:00 AM confirmed the above findings.</p>	A 242	<p>All instruments have been re sterilized and the date, time, load # and autoclave ID has been documented on each pouch and pack.</p> <p>The Director of Clinical services will facilitate an infection control training on November 30th, 2015 staff will be required to prepare for this training by reading WWH policy for decontamination and Sterilization techniques. During the training, the designated trainer will show the staff the proper way to wrap, pack, and label instruments to be sterilized. By the end of the training the staff will be asked to perform each one of these steps while evaluated by the trainer. A competency checklist will be documented and filed in the staff's personnel record.</p> <p>In order to ensure compliance, the Clinic Administrator will perform randomized tracer to address staff's competency and follow through of our policies and address training needs.</p>	11/30/15
A 245	TAC 139.49(d)(5)(F)(iii)(iv)(v) Infection Control Standards	A 245		11/30/15

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A 245	<p>Continued From page 11</p> <p>(F) Biological indicators.</p> <p>(iii) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.</p> <p>(iv) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.</p> <p>(v) All available items shall be recalled and reprocessed if a sterilizer malfunction is found. A list of all items which were used after the last negative biological indicator test shall be submitted to the administrator.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain a log for biological indicators (BI) that included time, load identification, and contents of the load. Also, the facility failed to follow their own policy.</p> <p>Findings include:</p> <p>Observation on 10/20/2015 at 10:15 AM revealed a "Pathology" room with one (1) Pelton Delta Q autoclave.</p> <p>An interview with Staff #3 on 10/20/2015 at 10:15 AM stated she was a medical assistant and the person responsible for the autoclave. Staff #3 stated, "I run a biological indicator (BI) test with the 1st load every day that the autoclave is ran."</p> <p>A review of the record titled, "Biological Indicator Log " on 10/20/2015 at 11:00 AM revealed the following: the time the biological was placed in the autoclave was left blank and the time the</p>	A 245	<p>A245</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are met by ensuring the Biological Indicator (BI) log is completed and accurate.</p> <p>All BI test performed after the survey conducted on 10/21/15 have been accurately documented on the BI log to include time and load ID, contents, and the 24 hr reading with the time it was run.</p> <p>The Director of Clinical Services will facilitate a training for all staff working in the pathology lab on how to run biological indicators (BI) and how to properly document the test and results of the spore test. The Director of Clinical Services will observe each staff run the BI test and document it on the log.</p> <p>The Clinic Administrator will monitor compliance with this standards by conducting an audit of the sterilization and BI logs on a monthly basis to ensure adequate competency, and address training needs.</p>	<p>11/30/15</p> <p>10/21/15</p>

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 10/21/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
A 245	Continued From page 12 biological was read 24 hours later was left blank. Also, the load identification and contents of the load was not documented on the biological log. A review of the log for the date 9/30/2015 revealed the control biological was left blank. A review of facility policy titled, "Procedure for Pathology" revealed the following: "Biological Indicators The efficacy of the sterilizing process will be monitored with reliable biological indicators. (i.e. Bacillus stearothermophilus) appropriate for the type of sterilizer used. A. These indicators will be included in one run each day of use per sterilizer. B. A log will be maintained with the load identification, biological indicator results, and identification of the contents of the load. C. If a test is positive, the sterilizer will immediately be taken out of service and will not be put back into service until it has been serviced and successfully tested. D. All available items will be recalled and reprocessed if a sterilizer malfunction is found." An interview on with Staff #3 on 10/20/2015 at 10:15 AM revealed the biological log was not completed and facility policy had not been followed.	A 245			
A 247	TAC 139.49(d)(5)(H)(i)(II)(III) Infection Control Standards (H) Maintenance of sterility. (i) Items that are properly packaged and sterilized shall remain sterile indefinitely unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of	A 247	A 247 The Clinic Administrator will be responsible for ensuring all Infection Control Standards are accurately followed by ensuring medication therapy protocol is followed.	11/30/15	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140007	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 10/21/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 247	Continued From page 13 being compromised. (ii) Medication or materials within a package that deteriorate with the passage of time shall be dated according to the manufacturer's recommendations. (iii) All packages shall be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item may not be used. The item shall be returned to sterile processing for reprocessing. This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to discard medication not administered in a timely manner. During a tour of the facility with the Administrator on 10/21/2015 at 9:46 AM observed a syringe on the second shelf of a rolling cart in the Pathology room. There were no staff members in the room. The Administrator was asked what is that syringe for and why was the syringe left unattended. The Administrator stated, "It was for today's procedure." Surveyor showed the syringe to the Administrator and the syringe was labeled "Lidocaine 10/20/2015." The syringe had been left from the the previous day procedures. An interview with the Administrator on 10/21/2015 at 9:46 AM confirmed the above findings.	A 247	The unused lidocaine syringe found on the rolling cart in the pathology room from the previous surgery day was immediately disposed of. The Clinical coordinator performed a thorough check of all procedure rooms, pathology lab and nurse's station to ensure there are no unused medications. An in service will be facilitated to all surgical staff in order to ensure their understanding on the proper way to prepare medications for each day of services, and how to dispose of all unused medications at the end of session. The Clinical Coordinator will be responsible for ensuring this practice is strictly followed, by conducting an end of day walk through and check of each procedure room, pathology lab, and nurses station. Findings will be immediately communicated to the Clinic Administrator.	
A 249	TAC 139.49(d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall ensure proper storage and handling of items in a manner that does not compromise the packaging of the product. (i) Sterilized items shall be transported so as to	A 249	A249 The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed.	11/30/15 12/9/15

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
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A 249	<p>Continued From page 14</p> <p>maintain cleanliness and sterility and to prevent physical damage.</p> <p>(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.</p> <p>(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.</p> <p>(iv) Storage of supplies shall be in areas that are designated for storage.</p> <p>This Requirement Is not met as evidenced by: Based on observation, and interview, the facility failed to store peel pouches in a position that was free of being crushed, bent, compressed, or punctured.</p> <p>FINDINGS:</p> <p>During a tour of the facility on 10/20/2015, multiple peel pouches were stored in a plastic container in the pathology room. Also, the peel pouches were found in a blue tote bag on a rolling cart that was used for storage of the sterile instruments.</p> <p>Approximately 20 peel packs were crushed and compressed in the plastic container which had no lid and was stored in the pathology room, where products of conception were examined and contaminated instruments were washed. The facility had no area designated for storage of sterile peel pouches.</p> <p>An interview with Staff #3 on 10/20/2015 at approximately 11:00 AM confirmed the above findings.</p>	A 249	<p>The Clinic Administrator along with the staff trained to work in the pathology and sterilization lab, have reorganized the area and identified storage space outside of the pathology and sterilization room. They have designated storage space on the surgical hall closet in order to adequately stack sterilized pouches in a position free of being crushed, bent, compressed or punctured.</p> <p>In addition a staff in service will be facilitated to ensure staff understands how to properly store packs and pouches.</p> <p>In order to monitor compliance with this requirement, the Clinic Administrator will conduct random weekly inspections of the sterilized stored instruments. Findings will be addressed during quality assurance meetings.</p>	

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NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF SAN ANTONIO		STREET ADDRESS, CITY, STATE, ZIP CODE 4025 E SOUTHCROSS BLVD BLDG 5 SUITE 30 SAN ANTONIO, TX 78222		
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A 255	Continued From page 15	A 255		
A 255	<p>TAC 139.49(d)(5)(K)(i)(ii)(iii) Infection Control Standards</p> <p>(K) Disinfection.</p> <p>(i) The manufacturer's written instructions for the use of disinfectants shall be followed.</p> <p>(ii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.</p> <p>(iii) Disinfectant solutions shall be kept covered and used in well-ventilated areas.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to follow the manufacturer's written instructions for the use of cold disinfectant (Cidex) utilized on surgical instruments. Also, the facility failed to provide a disinfectant log for the Cidex being utilized in the facility for the disinfection of surgical instruments.</p> <p>Findings:</p> <p>During the tour of the Pathology room on 10/21/21 at 9:47 AM revealed a large clear plastic container labeled Cidex. The container was covered, but there was no label to indicate when the Cidex was mixed. Also, under the sink in the pathology room was a gallon of open Cidex with no label as to when the container was open. There was a glass suction jar ¾ full with a green liquid substance and written on the side of the glass jar was Cidex. There was no label or date as to when the liquid substance was mixed.</p> <p>During the tour of the Pathology room (where cold disinfectant was located) on 10/20/2015 at</p>	A 255	<p>A255</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are being followed by ensuring the proper labeling and documenting of decontaminating solutions.</p> <p>Whole Woman's Health of San Antonio uses the Metrex disinfection log which contains all the information required by the manufacturer's instructions. (See Attached)</p> <p>This log tracks the date solution prep, expiration and staff preparing solution, this log is kept on a binder labeled Cidex OPA Plus log, and a memorandum directing staff to document on the solution's original container the date it was opened, and when it expires according to the manufacturer's instructions will be included in this binder as well as circulated during the infection control training scheduled for 11/30/15</p>	11/30/15

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A 255	<p>Continued From page 16</p> <p>10:45, Staff #3 was asked where the cold disinfectant log was. Staff #3 stated, "I don't have a disinfectant log." During a tour of the Pathology room on 10/21/2015 at 9:50 AM, a disinfectant log was observed, but the log was blank.</p> <p>A review of the log titled, "Solution Testing log Sheet for: Metriolde OPA" revealed the date solution was opened was 10/9/2015 and the expiration date was 12/23/2015. The OPA-Cidex is only stable for 14 days from day the solution is mixed. This log location/department was written as Path room/Sonography. Staff #3 was asked on 10/20/2015 at 10:45 AM what was the green substance in the glass jar under the sink in the Pathology room. Staff #3 stated, "I don't know that belongs to the sonographer."</p> <p>A review of the manufactures' guideline revealed the following: "CIDEX OPA Solution may be reused for up to a Maximum of 14 days provided the required conditions of ortho-phthalaldehyde concentration and temperature exist based upon monitoring described in the Direction for use. Do not rely solely on day in use. Concentration of this product during its reuse life must be verified by the CIDEX OPA Solution Test Strips prior to each use to determine that the concentration of orto-phthalaldehyde is above the MEC of 3%. The Product must be discarded after 14 days. Use CIDEX OPA Solution in a well-ventilated area and in closed containers with tight-fitting lids. If adequate ventilation is not provided by the existing air conditioning system, use in local exhaust hoods, or in ductless fume hoods/portable ventilation devices which contain filter media which absorb ortho-phthalaldehyde from the air."</p> <p>A review of the manufactures' guideline on the</p>	A 255	<p>The Cidex solution currently in use by the pathology staff has been placed in a container with a tight lit. The Cidex used to disinfect the ultrasound transducer will be placed in a glass jar labeled with date the solution was prepared and the expiration date.</p> <p>In order to ensure compliance with this requirement the Administrator will conduct a monthly audit of the Cidex log and a walk through of the pathology room to ensure this solution is properly stored and labeled.</p>	

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A 255	Continued From page 17 OPA gallon container revealed the following: "Usage: NO ACTIVATION IS REQUIRED. Record the date the container was opened on the container label, or in a log book. After opening, the solution remaining in the container may be stored for up to 75 days (providing the 75 days does not extend past the expiration date on the container) until used. Record the date the solution was poured out of the original container into a secondary container in a log book (separate from the one mentioned above), or on a label affixed to the secondary container. The solution in the secondary container can be used for a period up to 14 days. The product must be discarded after 14 days even if the CIDEX OPA Solution Test Strip indicates a concentration above the MEC (Minimum Effective Concentration)." An interview with the Staff #1 on 10/21/2015 at 11:00 AM confirmed the above findings.	A 255		
A 257	TAC 139.49(d)(5)(L)(II)(I - V) Infection Control Standards (L) Performance records. (II) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include: (I) the sterilizer identification; (II) sterilization date and time; (III) load number; (IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts); (V) Identification of operator(s);	A 257	A257 The clinic administrator will be responsible for ensuring all infection control standards are strictly followed by ensuring the Autoclave Load Log is completed and adequately tracks the performance of the autoclave.	11/30/15

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A 257	Continued From page 18 This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain performance records for the autoclave during operation that included pressures, temperatures, and times at desired temperature and pressure. Findings include: Observation on 10/20/2015 at 10:15 AM revealed a "Pathology" room with one (1) Pelton Delta Q autoclave. An interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclave. A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the load identification, date, time, duration and temperature of exposure phase during the operational phase of the autoclave. A continued interview with Staff #3 confirmed these were all the autoclave records available.	A 257	Whole Woman's Health of San Antonio has updated its Autoclave Load Log to include documentation of temperature and pressure of each autoclave during operation. Even though this information was not previously documented on the log, the staff sterilizing the instruments always confirmed that the autoclave was indeed reaching the required temperature and pressure to ensure decontamination and sterility of the instruments. A staff in service will be facilitated by the director of clinical services to ensure all staff understands the proper way to document the performance of each autoclave for each load. In order to monitor compliance with this requirement the clinic administrator will conduct a monthly audit of the autoclave load log and address adequate documentation and training needs.	
A 258	TAC 139.49(d)(5)(L)(ii)(VI)(VII) Infection Control Standards (L) Performance records. (ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall	A 258		11/30/15

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A 258	<p>Continued From page 19</p> <p>be maintained either manually or machine generated and shall include: (VI) results of biological tests and dates performed; and (VII) time-temperature recording charts from each sterilizer (if not provided on sterilizer recording charts).</p> <p>This Requirement Is not met as evidenced by: Based on observation, record review, and interview, the facility failed to maintain performance records for the autoclave during operation that included pressures, temperatures, and times at desired temperature and pressure.</p> <p>Findings include:</p> <p>Observation on 10/20/2015 at 10:15 AM revealed a designated " Pathology" room with one (1) Pelton Delta Q autoclave.</p> <p>An interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclaves.</p> <p>A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the time, duration and temperature of exposure phase during the operational phase of the autoclave.</p> <p>An interview with Staff #3 on 10/20/2015 at 10:45 AM confirmed there were no recordings of the time-temperature from the autoclave.</p>	A 258	<p>A 258</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are strictly followed. Whole Woman's Health of San Antonio has updated its Autoclave Load Log to include documentation of temperature and pressure of each autoclave during operation. Even though this information was not previously documented on the log, the staff sterilizing the instruments always confirmed that the autoclave was indeed reaching the required temperature and pressure to ensure decontamination and sterility of the instruments.</p> <p>A staff in service will be facilitated by the director of clinical services to ensure all staff understands the proper way to document the performance of each autoclave for each load.</p> <p>In order to monitor compliance with this requirement the clinic administrator will conduct a monthly audit of the autoclave load log and address adequate documentation.</p>	11/30/15

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A 259	Continued From page 20	A 259		
A 259	<p>TAC 139.49(d)(5)(M) Infection Control Standards</p> <p>(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review to the facility within two hours of request by the department.</p> <p>This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to maintain preventive maintenance records for the autoclave.</p> <p>Findings include:</p> <p>Observation on 10/20/2015 at 10:15 AM revealed a designated " Pathology" room with one (1) Pelton Delta Q autoclave.</p> <p>An interview with Staff #3 on 10/20/2015 at 10:45 AM revealed she was the medical assistant and the person responsible for the autoclaves. Staff #3 was asked to produce all logs and records for the autoclaves.</p> <p>A review of the record on 10/20/2015 revealed the records/logs presented for the autoclave did not show any documentation of the time, duration and temperature of exposure phase during the operational phase of the autoclave.</p>	A 259		11/30/15

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A 259	Continued From page 21 An interview with Staff #3 on 10/20/2015 at 10:45 AM confirmed there were no recordings of the time-temperature from the autoclave.	A 259			

Exhibit 7.2
Legal Opinion to ISDH

PRINTED: 12/02/2015
FORM APPROVED

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008036	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 000	<p>TAC 139 Initial Comments</p> <p>Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p> <p>An entrance conference was held with the facility clinical coordinator and another facility staff member on the morning of 11/10/15. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.</p> <p>Continued licensure is recommended, with an approved plan of correction.</p> <p>An exit conference was held with the facility clinical coordinator and another administrative staff on the evening of 11/10/15. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p>	A 000	<p><i>Accepted 1/8/16</i></p>	12/28/15
A 128	<p>TAC 139.41(a) Policy Development and Review</p> <p>(a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following:</p>	A 128	<p>A126</p> <p>The Clinic Administrator will be responsible for the conduct of the facility, and for the implementation, enforcement and monitoring of the written policies governing the facility.</p> <p>The clinic Administrator has placed a purchase order for small red biohazard bags, as well as small biohazard stickers as a backup option for storing pathological waste in the biohazard freezer.</p>	

SOD - State Form
LABORATORY

LABORATORY PROVIDER'S SIGNATURE

TITLE

(X6) DATE

STATE FORM

6806

RNHO11

If continuation sheet 1 of 7

LVM, Clinic Administrator

01/06/2016

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008038	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 11/10/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP			STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE	
A 126	<p>Continued From page 1</p> <p>This Requirement is not met as evidenced by: Based on a review of policies, tour of the facility, and interview the facility failed to enforce written policies governing the facility's total operation, to provide health care in a safe and professionally acceptable environment.</p> <p>Findings included:</p> <p>Facility procedure entitled, "Procedure for pathology" stated in part, "10. The staff member will dispose of the POC into a small biohazard bag. When that bag is full or at the end of a session (whichever comes first), the staff member will place that bag into another Ziploc and put it into the path lab freezer."</p> <p>During a tour of the facility on 11/10/15 it was observed that the freezer that the biohazard freezer contained approximately 5 unlabeled plain Ziploc bags containing POC (products of conception). The POC was not in a labeled biohazard bag.</p> <p>In an interview on 11/10/15, staff member #2 confirmed that all POC should be placed in a biohazard bag prior to being placed in a Ziploc bag and stored in the designated freezer.</p>	A 126	<p>An In Service will be facilitated to reiterate to staff that when working pathology, the POC should be placed in a small red biohazard bag to be stored in the freezer, even though all the small bags will be placed in a large biohazard bag and container to be transported out of the building. In the event the clinic has to use zip lock bags, a biohazard sticker will be placed on the outside of the bag in order to properly identify the bag before placing it inside the biohazard freezer.</p> <p>In order to monitor compliance with this requirement, the clinic administrator will conduct randomized tracers on staff working in the pathology lab, findings will be discussed during the quality assurance meetings.</p>		
A 197	<p>TAC 139.48(1)(A) Physical & Environmental Requirements</p> <p>The physical and environmental requirements for a licensed abortion facility are as follows.</p>	A 197	<p>A197</p> <p>The Clinic Administrator will be responsible for ensuring all physical and environmental requirements are accurately followed.</p>	01/04/15	

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008036	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 197	<p>Continued From page 2</p> <p>(1) A facility shall: (A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;</p> <p>This Requirement is not met as evidenced by: Based on observation and an interview with staff, the facility failed to have a safe and sanitary environment that was maintained to protect the health and safety of patients and staff at all times.</p> <p>Findings were:</p> <p>During a tour of the facility on 11-10-15, the following observations were made:</p> <ul style="list-style-type: none"> - The vinyl cover on the exam table in the sonograph room contained tears, which can harbor bacteria and prevent the exam table from being completely cleaned. - Examination of the medications in the emergency cart revealed 2 vials of Calcium Gluconate 10 % Injectable 10 ml with an expiration date of 10/15, 1 bag of Lactated Ringers 500 ml IV with an expiration date of 5/2015, 1 ET Tube with brown discoloration/staining visible on the packaging, and 1 suction tubing with a torn/open packaging. The expired medications and damaged supplies were available for patient use. <p>The above was confirmed in an interview, with staff #2 during a tour of the facility on 11-10-15.</p>	A 197	<p>The creases on the vinyl cover on the exam table in the sonogram room will be repaired. This exam table won't be in use until the creases have been fixed.</p> <p>Due to a clerical error expired medications were kept with current medications in the crash cart, those have now been removed and properly discarded. Staff has received training on how to evaluate the need to replace medical supplies that do not have expiration dates, the ET and suction tubing have been removed from the cart, and have been replaced by new ones.</p> <p>In order to ensure compliance with the physical and environmental requirements mandated by the state, the clinic administrator will conduct a physical walk through of the facility to inspect the appearance and functionality of all equipment. Findings will be addressed during the quality assurance meetings.</p>	

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008030	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 201	Continued From page 3	A 201		
A 201	TAC 139.48(1)(E)(F) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (E) store hazardous cleaning solutions and compounds in a secure manner and label substances; (F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of §§229.161 - 229.171 of this title (relating to Texas Food Establishments); This Requirement is not met as evidenced by: Based on a tour of the facility, the facility failed to store hazardous cleaning solutions and compounds in a secure manner. Failure to do so increases the risk of harm to patients. Findings were: During a tour of the facility on 11-10-15, the unlocked laundry room contained items including disinfectant spray, air freshener spray, germicidal wipes, all-purpose spray cleaner and bleach. The above was confirmed in an interview, with staff #2 on 11-10-15 during a tour of the facility.	A 201	A201 The Clinic administrator will be responsible for ensuring the physical and environmental requirements for the facility are followed accurately. The Clinic will install locks on the laundry closet cabinets, and ensure all cleaning products are locked during patient care hours. A staff in service will be facilitated on 01-15-16 to ensure all staff is aware of ensuring these products are to be locked during patient care. The clinic Administrator will ensure compliance with this requirement by conducting random walk through of the facility. Findings will be addressed during quality assurance meetings.	01/15/16
A 249	TAC 139.49(d)(5)(J)(i)(ii)(iii)(iv) Infection Control Standards J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall	A 249		

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008038	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
NAME OF PROVIDER OR SUPPLIER WHOLE WOMANS HEALTH OF MCALLEN LP		STREET ADDRESS, CITY, STATE, ZIP CODE 802 SOUTH MAIN STREET MC ALLEN, TX 78501		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
A 249	<p>Continued From page 4</p> <p>ensure proper storage and handling of items in a manner that does not compromise the packaging of the product.</p> <p>(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage.</p> <p>(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.</p> <p>(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.</p> <p>(iv) Storage of supplies shall be in areas that are designated for storage.</p> <p>This Requirement is not met as evidenced by: Based on observation, and interview, the facility failed to store peel pouches in a position that was free of being crushed, bent, compressed, or punctured.</p> <p>FINDINGS:</p> <p>During a tour of the facility on 11/10/15, multiple peel pouches were observed stored on a counter in the pathology room. Approximately 10 peel packs were crushed and compressed, the adhesive seal across the bottom of these peel packs was observed to be wrinkled with small gaps present, presenting a risk for contamination. The tacking of the packs also presented a risk of the packaging being punctured.</p> <p>An interview with Staff #3 on 11/10/15, confirmed the above findings.</p>	A 249	<p>A249</p> <p>The Clinic Administrator will be responsible for ensuring all infection control standards are accurately followed.</p> <p>The Clinic Administrator along with the staff trained to work in the pathology and sterilization lab, will reorganize the area and designate storage space on the clean side cabinets to carefully stack sterilized pouches in a position free of being crushed, bent, compressed or punctured.</p> <p>In addition a staff in service will be facilitated to ensure staff understands how to properly store packs and pouches.</p> <p>In order to monitor compliance with this requirement, the Clinic Administrator will conduct random weekly inspections of the sterilized stored instruments. Findings will be addressed during quality assurance meetings.</p>	01/15/16

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008036	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
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A 356	Continued From page 5	A 356		
A 356	<p>TAC 139.56(b)(c) Emergency Services</p> <p>(b) The facility shall have the necessary equipment and personnel for cardiopulmonary resuscitation as described in §139.59 of this title (relating to Anesthesia Services).</p> <p>(c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities.</p> <p>This Requirement is not met as evidenced by: Based on a review of personnel files and an interview with staff, the facility failed to ensure that all direct care personnel were competent in and maintained current certification in cardiopulmonary resuscitation (CPR), as there was no documented evidence of hands-on skills practice and in-person assessment and demonstration of CPR skills. This presents a risk, as staff may not be competent to respond in a medical emergency.</p> <p>Findings included:</p> <p>A review of personnel files revealed that 3 of 6 direct staff members at facility (#1, 2, and 4) obtained cardiopulmonary resuscitation (CPR) through an online resource that contained no evidence of hands-on skills practice, an in-person assessment and/or demonstration of CPR skills. In an interview, on 11/10/15, staff member #2 confirmed that the online course did not contain hands-on skills practice, an in-person assessment and/or demonstration of CPR skills.</p>	A 356	<p>A356</p> <p>The Clinic Administrator will be responsible for ensuring all personnel complies with emergency services requirements.</p> <p>All staff members will receive Cardiopulmonary resuscitation (CPR) training by January 4, 2016.</p> <p>Documented evidence of hands on skills practice and in person assessment will be placed in personnel files. The Clinic Administrator will ensure compliance with this requirement by conducting monthly audits of the personnel files, and scheduling the proper recertification as needed.</p>	01/04/16

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 008036	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/10/2015
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A 356	Continued From page 6 Review of the Health & Safety Institute and the National Safety Council website found at http://news.hsi.com/onlineonlycpr reveals that, "No major nationally recognized training program in the United States endorses certification without practice and evaluation of hands-on skills. According to the Occupational Safety and Health Administration (OSHA) online training alone does not meet OSHA first aid and CPR training requirements."	A 356		

You are here: Home / Press Releases / Over \$83,000 in Fines Assessed in Texas for Illegal Dumping of Aborted Baby Remains



Over \$83,000 in Fines Assessed in Texas for Illegal Dumping of Aborted Baby Remains

December 1, 2011 By Operation Rescue 3 Comments

Austin Texas – The Texas Commission on Environment Quality has released documents to Operation Rescue that show two Texas abortion clinics and the disposal company Stericycle have been slapped with fines in excess of \$83,000 for illegal dumping of aborted baby remains.

The fines are the result of complaints filed by Operation Rescue against Whole Woman's Health of McAllen and Austin after a three-month undercover investigation. The TCEQ then conducted its own investigation and broadened the case to include Stericycle. In June, the TCEQ notified Operation Rescue that the two abortion clinics and Stericycle had all been cited for violations involving the improper disposal of human fetuses.

Fines for the violations were finalized three months later. TCEQ also ordered the abortion clinics and Stericycle to make specific changes in their operations.

The two abortion clinics also received a deferral of twenty percent of their fines on the same compliance contingency. However, if the TCEQ finds that they are not satisfactorily complying with the order, they will be required to pay the full amount.

"Our investigation only scratched the surface of what is really going on at abortion clinics in Texas. These hefty fines totally over \$83,000 show that the violations we discovered were valid and serious," said Operation Rescue President Troy Newman. "We can only imagine what

- Whole Woman's Health of McAllen was fined at total of \$17,430. It is required to make monthly payments of \$385.
- Whole Woman's Health of Austin was ordered to pay a total of \$22,980. It must pay off its fine with \$510 payments each month.
- Stericycle received the largest fine of \$42,612, which was paid in one lump sum minus twenty percent, which is deferred contingent upon satisfactory future compliance.

the public's welfare." In addition to the TCEQ fines, ten abortionists must answer to the Texas Medical Board for other abortion abuses discovered by Operation Rescue. Word on the extent of their discipline is expected in February.



Dumpsters behind Whole Women's Health were open and spilling trash. Infectious waste and other hazardous materials, and private medical records were illegally dumped there.

would be found if every abortion clinic was thoroughly investigated."

"Abortion clinics cannot be trusted to follow the law or tell the truth about it even if they are caught," said Newman. "Time and again we have seen that abortionists have the attitude that they are above the law.

Abortion clinics need to be inspected and violations strictly enforced for the sake of

(<http://dailycaller.com/>)



EXHIBIT 9
Legal Opinion to ISDH

HEALTH

(<http://dailycallernewsfoundation.org/>)

 (<http://www.twitter.com/dailycaller>)  (<http://www.facebook.com/DailyCaller>)  (<https://plus.google.com/104273926598894453484/posts>)  (<https://www.linkedin.com/company/the-daily-caller>)

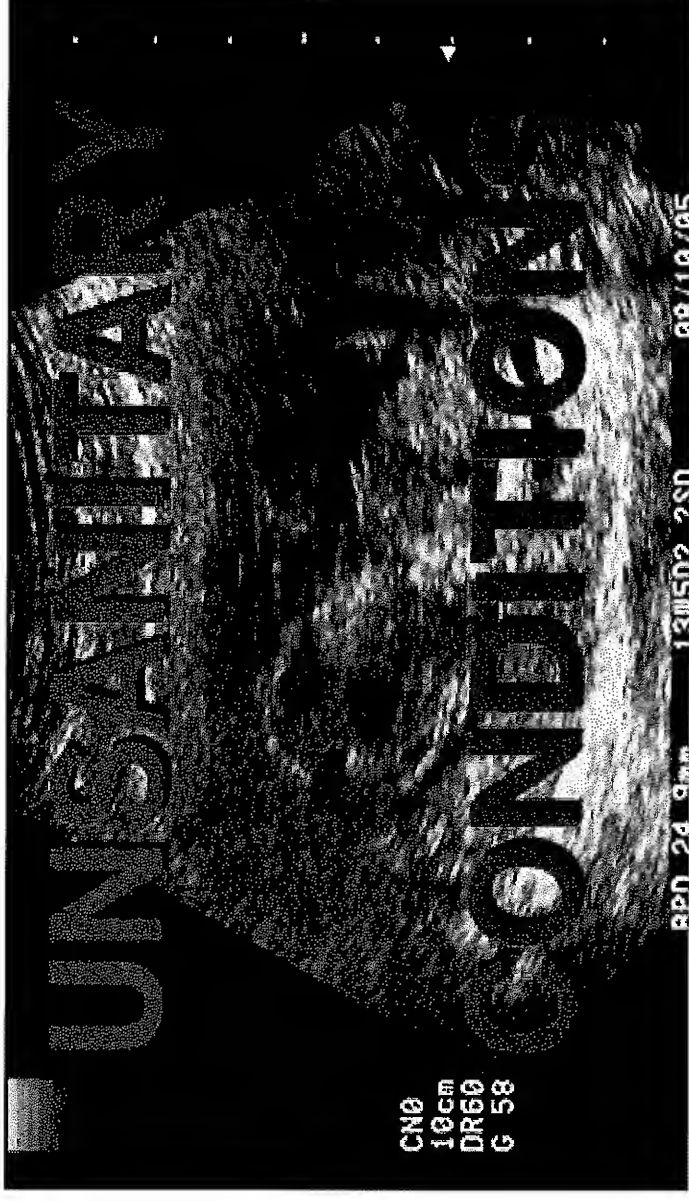
Abortion Clinics Are Crawling With Dirty Health Violations, Report Finds

by GRACE CARR, reporter

(<http://dailycaller.com/author/grace-carr/>)

11:57 AM 10/27/2017





A string of abortion clinics across the country continues to violate the law and jeopardize the health and lives of women by failing to keep clinics clean and train staff adequately, according to the Texas Department of State Health Services.

A slew of Whole Woman's Health (WWH) abortion clinics miserably failed inspection reports between 2011 and 2017, [the Free Beacon reported \(http://freebeacon.com/issues/texas-abortion-clinics-marred-health-safety-issues-inspection-reveals/?utm_source=Freedom+Mail&utm_campaign=eb64ddce41-EMAIL_CAMPAIGN_2017_10_26&utm_medium=email&utm_term=0_b5e6e0e9ea-eb64ddce41-46249161\)](http://freebeacon.com/issues/texas-abortion-clinics-marred-health-safety-issues-inspection-reveals/?utm_source=Freedom+Mail&utm_campaign=eb64ddce41-EMAIL_CAMPAIGN_2017_10_26&utm_medium=email&utm_term=0_b5e6e0e9ea-eb64ddce41-46249161) in conjunction with the nonprofit And Then There Were None (ATTWN).

"Anyone who cares for women's health and safety should want abortion facilities to be frequently inspected, no matter what their position is on abortion. Because this is a health and safety issue, and just because it has to do with a hot button topic, does not mean that the abortion industry should get a free pass," Arina Grossu, Center for Human Dignity

Director at the Family Research Council, told the Free Beacon. “Restaurants and tanning salons and vet clinics, they’re all more closely regulated than the abortion industry.”

Medical instruments were unsterile and rusty, medication had expired, staff were inadequately trained, and the facilities were dirty enough to constitute health hazards, the inspection reports found. The inspections also discovered faulty patient records, disregard for informed consent, undercover calls and visits from minors, and waiting period violations. The Beaumont, Texas WWH clinic did not even have a registered nurse on staff in 2011.

A WWH abortion clinic in McAllen, Texas was in disrepair, with stains, cracks in exam tables and holes in the flooring, a 2016 study found. ATTWN’s 2017 report also found missing stocks of fentanyl, which has responsible for the rise hundreds of thousands of deaths in the ongoing opioid crisis. **(RELATED: Opioid Crisis: A Daily Game Of Russian Roulette)** (<http://dailycaller.com/2017/09/29/opioid-crisis-a-daily-game-of-russian-roulette/>).

“I was appalled at the state of the Austin Whole Woman’s Health. It looked more like a prison than an actual facility where patients went for healthcare. Disgusting does not do it justice,” ATTWN founder Abby Johnson said. The WWH clinic in Austin even had blood on the walls, she noted.

“What we see in the abortion industry across the country is that inspections are done, people come in, they’re cited for violations, they make a temporary plan to improve, a year later an inspector comes in, they cite them for the same violations, they make a temporary plan to improve ... it’s the same cycle, over and over again,” she said. “If we’re going to say that we’re for women, and we’re for protecting women, then this was sort of a common sense measure.”

More than 220 abortion clinics between 2008 and 2016 — including six (<http://unsafe.aul.org/wp-content/uploads/2016/12/Unsafe-Chart.pdf>) WWH clinics — were cited for 1,400 health and safety violations, according to a 2016 Americans United For Life (AUL) report (<http://www.lifeissues.org/wp-content/uploads/2017/01/UNSAFEreport.pdf>).

WWH was also involved in a lengthy lawsuit, Whole Woman’s Health v. Hellerstedt (<http://www.scotusblog.com/case-files/cases/whole-womans-health-v-cole/>), regarding restrictions on abortion services.



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EXHIBIT 10
Legal Opinion to ISDH



Why Should Abortionists Have Admitting Privileges? Look at These Botched Abortions at Just One Clinic

9 STATE (HTTP://WWW.LIFENEWS.COM/CATEGORY/STATENEWS/)

CHERYL SULLINGER MAY 19, 2014 | 11:53AM AUSTIN, TX



Whole Women's Health of Austin where documents show a string of abortion-related medical emergencies.

After the passage in Texas last summer of an historic pro-life law known as HB2, hardly a week as gone by without articles penned by abortion supporters lamenting the new regulations as nothing more than a ploy to shut down abortion clinics.

Amy Hagstrom-Miller, President of the Whole Women's Health abortion clinic chain, is perhaps one of the loudest voices condemning the new law that has already closed 20 Texas abortion clinics — including two of hers. Once the rest of the provisions take effect this September, it is likely that only six abortion clinics will remain in the Lone Star State.

(<http://lifeneeds.wpengine.netdna-cdn.com/wp-content/uploads/2014/05/wholewomens.jpg>) Causing particular angst has been the requirement that abortionists maintain hospital privileges within 30 miles of their clinics.

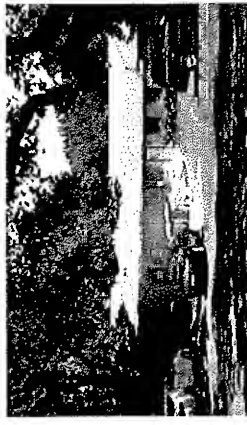
“Our elected officials lied to all of us, HB2 has nothing to do with improving women's health and safety; but rather it is a proven and successful strategy to end safe abortion care for women in Texas,” opined Hagstrom-Miller just last month.

However, Operation Rescue has received three 911 records from just one of Hagstrom-Miller's abortion clinics, Whole Women's Health of Austin, over a 30-day period in 2012 that shows the clinic has a poor track record when it comes to women's safety.

“This documentation loudly refutes Ms. Hagstrom-Miller's fantasy that the hospital privilege requirement and other safety regulations in the Texas law have nothing to do with patient safety. In fact, if patient safety was more of a concern to abortion clinics, perhaps we wouldn't see the long line of women being transported to the hospital, and in some cases, the morgue,” said Troy Newman, President of Operation Rescue.

The following incidents were documented through 911 Computer Aided Dispatch Transcripts obtained by Operation Rescue:

- March 17, 2012: A 20-year old female patient was transported to Saint David's Hospital suffering from an allergic reaction. This incident was of moderate severity, but required emergency hospital intervention.
- April 2, 2012: A 34-year old female was rushed to North Austin Hospital with a priority designation that indicated her condition was life-threatening. In fact, paramedics responding to the call upgraded the patient's priority upon assessment of her condition. The WWH caller told dispatchers that the woman was breathing and conscious, but not alert. She was suffering abdominal pain and vomiting while at the clinic. This was the last serious of the three incidents.
- April 18, 2012: A sick and vomiting 22-year old female patient was transported to St. David's Hospital. Records indicate that she suffered “no priority symptoms,” nevertheless, she required emergency hospital treatment that could not be provided at WWH.



Whole Women's Health of Austin where documents show a string of abortion-related medical emergencies.

This 30-day snapshot of emergencies at just one Whole Women's Health abortion clinic shows that these facilities are not equipped to handle even the least serious of complications that can be expected to occur at abortion clinics, much less the life-threatening ones.

When emergencies occur, it is imperative that there is continuity of patient care so that emergency treatment is not delayed, especially in life-threatening situations, such as was inflicted upon the 34-year old patient on April 2, 2012. Even a short delay while hospital physicians struggle to diagnose a patient's condition, as we saw in the case of Tonya Reaves (<http://www.operationrescue.org/archives/planned-parenthood-abortionist-evaded-blame-shifted-in-death-of-tonya-reaves-deposition-shows/>), who died at a Chicago, Illinois Planned Parenthood clinic in 2013 can mean the difference between life and death. The hospital privilege requirement adds a layer of protection for women who suffer abortion complications from suffering a delay in care.

Despite Ms. Hagstrom-Miller's hysteria, the Texas law — particularly the local hospital privilege requirement — is all about patient safety. Given the frequency with which Whole Women's Health sends patients to the hospital emergency rooms for medical help the clinics cannot provide, these laws are critically needed to ensure that women get the care they need.

If the law results in the closure of abortion clinics that cannot guarantee patient safety or continuity of care in the event of a medical emergency, then it is in the best interests of women for those abortion clinics to close. Hagstrom-Miller's attitude only reveals that the health and safety of women take a back seat to her financial profit margin, which is currently enhanced by cutting corners on women's lives.

[View March 17, 2012 CAD transcript \(http://operationrescue.org/pdfs/CAD-WWHAustin-03172012.pdf\)](http://operationrescue.org/pdfs/CAD-WWHAustin-03172012.pdf)

[View April 2, 2012 CAD transcript \(http://operationrescue.org/pdfs/CAD-WWHAustin-04022014.pdf\)](http://operationrescue.org/pdfs/CAD-WWHAustin-04022014.pdf)

[View April 18, 2012 CAD transcript \(http://operationrescue.org/pdfs/CAD-WWHAustin-04182012.pdf\)](http://operationrescue.org/pdfs/CAD-WWHAustin-04182012.pdf)

LifeNews.com Note: Cheryl Sullenger is a leader of Operation Rescue (<http://www.OperationRescue.org>), a Kansas-based pro-life that monitors abortion practitioners and exposes their illegal and unethical practices. The group is known for serving as a watchdog of Planned Parenthood and other abortion businesses.

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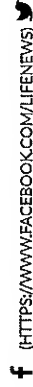
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State	City	Abortion Provider	Incident(s) Description	Documentation/Resources
IL	Peoria	National Health Care Services (now named Whole Women's Health of Peoria)	<p>The Illinois Department of Public Health noted on July 6, 2011 that deficiencies and violations at National Health Care Services included:</p> <ul style="list-style-type: none"> - Staff not adequately trained was performing duties they should not have the potential for cross contamination of contagions. - Water temperature was not hot enough. - Snack nuts and packages of cookies were on the crash cart. - Failure to ensure staff training for emergency or non-emergency situations were conducted. - Facility failed to ensure medical histories and complete physical examinations were reviewed by the physician prior to the procedure. - Facility failed to ensure personnel administering intravenous sedation was qualified in the State of IL to administer anesthesia, <p>RNs administering moderate sedation had multiple clinical responsibilities, were not ACLS certified and the physicians were not privileged to administer moderate sedation. No documentation to indicate physicians were ACLS certified.</p>	<p>EXHIBIT 11 Legal Opinion to ISDH</p> <p>IL Department of Public Health Division of Health Facilities Standards: Statement of Deficiencies and Plan of Correction. Date of Survey: July 6,</p>

MD	Baltimore	Whole Women's Health Baltimore	<p>The Statement of Deficiencies Report from the February 22, 2013 inspection of Whole Women's Health Baltimore found deficiencies included:</p> <ul style="list-style-type: none"> ■ Failure to secure the medical waste sharps container and protect the safety of patients. ■ Failure to implement their policy and procedures for the use and storage of medications. 	<p>Maryland Department of Health and Mental Hygiene, Statement of Deficiencies and Plan of Correction, Whole Women's Health Baltimore, Inspection Date February 22, 2013, <i>available at</i> http://abortiondocs.org/wpcontent/uploads/2014/11/Whole-Womens-Health-Baltimore-Initial-Survey-2-22-2013.pdf</p>
NC	Chapel Hill	Women's Health Alliance	<p>The Statement of Deficiencies Report from the April 3, 2014, inspection of Women's Health Alliance found the following deficiencies:</p> <ul style="list-style-type: none"> - Failure to have a witnessed voluntarily-signed informed consent for each surgery or procedure in 1 of 4 clinic records reviewed of patients that had abortion procedures. - Failure to verify the patient's full and true name for 4 of 4 patients who had abortion procedures. - Failure to maintain a daily procedure log of all patients receiving abortion services along with type of procedure, time of procedure, and Name of the Registered RN on duty. - Failure to ensure medications were administered by a RN or LPN in accordance with the State of NC for 2 of 2 patients who were administered medications and had a surgical abortion procedure performed. - Failure to ensure sterile instruments were not outdated and failed to ensure autoclave testing was performed per clinic policy. 	<p>North Carolina Division of Health Service Regulation, Statement of Deficiencies, Women's Health Alliance, for inspection on April 3, 2014, <i>available at</i> https://www2.ncdhhs.gov/dhsr/a-hc/sods/2014/20140403-933088.pdf</p>

			<ul style="list-style-type: none"> - Failure to ensure medications were administered by a RN or LPN in accordance with the State of NC for 2 of 2 patients who were administered medications and had a surgical abortion procedure performed. - Failure to ensure sterile instruments were not outdated and failed to ensure autoclave testing was performed per clinic policy. Interview with the administrative staff confirmed the staff did not follow the clinic's infection control policy for ensuring sterile items were not out of date/expired. 	
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**APPLICATION FOR LICENSE
TO OPERATE AN ABORTION CLINIC**

State Form 52233 (R3 / 3-14)
Approved by State Board of Accounts, 2014
Indiana State Department of Health-Division of Acute Care
(Pursuant to IC 16-21-2 and 410 IAC 28)

Division of Acute Care Use Only

Date Received (mm/dd/yyyy) _____ Date Approved (mm/dd/yyyy) _____ Date Rejected (mm/dd/yyyy) _____

Please Type or Print Legibly.

SECTION I - TYPE OF APPLICATION

Application (Check appropriate item.)

☒ New Facility ☐ Renewal ☐ Change of Ownership (Anticipated date of Sale/Purchase/Lease (mm/dd/yyyy)) _____
Submit a dated and signed copy of the bill of sale, lease or other document of transfer.

SECTION II - IDENTIFYING INFORMATION

A. Abortion Clinic Location

Name of Abortion Clinic

Whole Woman's Health Alliance

Street Address (number and street)

3611 Lincoln Way West

City

South Bend

County

St. Joseph

P.O. Box

ZIP Code +4

46626-1411

Telephone Number

()

Fax Number

()

Abortion Clinic e-mail address: _____

Internet Web Address: _____

B. Mailing Address (If different from abortion clinic location)

Street Address (number and street)

P.O. Box

City

County

ZIP Code +4

C. Licensee/Ownership Information

Licensee: The applicant entity as registered with the secretary of state

Whole Woman's Health Alliance

Street Address (number and street)

1812 Centre Creek Drive, Suite 205

City

Austin

State

Texas

P.O. Box

ZIP Code+4

78764

Telephone Number

(512) 835-8858

Fax Number

(512) 835-8808

EIN Number

46-5318393

Fiscal Year End Date (mm/dd)

12/31

D. Services provided under this license:

Code items 1 and 2 as follows: 1. Provided directly by employee(s), 2. Provided by a contract service, 3. Both 1 and 2.

1. Ancillary Services: ☐ Laboratory; CLIA Certificate Number _____ ☐ Radiology ☐ Counseling

☒ Family Planning ☐ Pharmacy ☐ Other (List): _____

2. Surgical Services: ☐ Gynecology ☐ Other (List): _____

For item 3, indicate the total number of individuals (employees plus contractors) working in this clinic. This includes hourly, part-time, and full-time persons.

3. Staffing: Physicians: ☒ Registered Nurses: ☐ Licensed Practical Nurses: ☐

Licensed Social Workers: ☐ Other (List title and number): 1ACP

E. Number of Procedure Rooms Utilizing:

Local analgesia/anesthetic ☒

Moderate/Conscious Sedation ☒

F. Type of Entity:

For Profit

- ☐ Individual
☐ Partnership
☐ Corporation
☐ Limited Liability Company
☐ Sole Proprietorship
☐ Other (specify) _____

Non-Profit

- ☐ Church Related
☐ Individual
☐ Partnership
☒ Corporation
☐ Limited Liability Company
☐ Other (specify) _____

Government

- ☐ State
☐ County
☐ City
☐ City/County
☐ Hospital District
☐ Federal
☐ Other (specify) _____

G. Officers of the business entity is not required

Position	Name	Signature
President/Chairman/CEO	Am. Henderson	
Vice President/Vice Chairman/CFO	N/A	
Treasurer	Blanca Tolson	
Secretary	John R. Burt	

H. Current and Prior Directors

Name	Signature	Signature
N/A		

I hereby declare that the information provided in this application is true and correct, and that I am not aware of any information that would cause this application to be false or misleading.

I understand that the information provided in this application is confidential and that I am not to disclose this information to any other person without the prior written consent of the Board of Directors.

Signature of the Medical Director: *Jeffrey D. Kay*
 Printed Name and Title: Jeffrey D. Kay, M.D. Med Dir
 Date of Signature (month/year): 07/25/2017
 Signature of the Clinic Administrator: _____
 Printed Name and Title: _____
 Date of Signature (month/year): _____

See the following page for instructions regarding licensure fees and submission of this application.

G. Officers (If the business entity is incorporated)

Position	Name	Address/City/State/ZIP
President/Chairperson/CEO	Amy Hopstrom Miller	1812 Centre Creek Drive, Suite 205, Austin, Texas, 78754
Vice-President/Vice-Chairperson/COO	N/A	
Treasurer/CFO	Branda Tubert	1812 Centre Creek Drive, Suite 205, Austin, Texas, 78754
Secretary	John H. Bucy II	1812 Centre Creek Drive, Suite 205, Austin, Texas, 78754

H. Ownership and/or Change in Ownership:

List names and addresses of individuals or organizations having direct or indirect ownership or controlling interest of five percent (5%) in the applicant entity. Indirect ownership interest is an entity that has an ownership interest in the applicant entity. Ownership in any entity higher in a pyramid than the applicant constitutes indirect ownership. (Use additional sheet if necessary.)

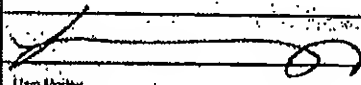
Name	Business Address/City/State/ZIP	EIN Number
N/A		

CERTIFICATION OF APPLICATION

The undersigned hereby makes application for a license to operate an Abortion Clinic (Clinic) in the State of Indiana, and in support of this application, represents and shows that the owner(s) and operator(s) are of reputable and reasonable character, are able to comply with the Abortion Clinic statutes, IC 16-21-2-215 and IC 16-34, and the rules promulgated there under, 410 IAC 26 and will operate and maintain this clinic in accordance with those rules.

I certify that the operational policies of the clinic will not provide for discrimination based upon race, color, creed, or national origin.

I swear and affirm under the penalty of perjury that all statements made in this application and any attachments thereto are correct and complete and that I will comply with all regulations, laws, and rules governing the licensing of clinics in Indiana.

Signature of the Medical Director:	
Printed Name and Title:	Jessie D. Glavin, MD, DO
Date of Signature (mm/dd/yyyy):	07/25/2017
Signature of the Clinic Administrator:	
Printed Name and Title:	Liam Morley
Date of Signature (mm/dd/yyyy):	10/03/2017

See the following page for Instructions regarding licensure fees and submission of this application.

License Fee

Select the appropriate fee based upon the total number of first trimester procedures as reported to the Indiana State Department of Health (ISDH) on the Terminated Pregnancy Report (State Form 36526).

Check One	Total First Trimester Procedures in the Clinic	Fee
<input checked="" type="checkbox"/>	Zero to 799	\$500.00
<input type="checkbox"/>	800 to 3,499	\$1,000.00
<input type="checkbox"/>	3,500 to 6,999	\$2,000.00
<input type="checkbox"/>	7,000 and above	\$3,000.00

Indiana Hospital Council; 414 IAC 1-1-3

Enclose the following:

1. A completed Application for License to Operate an Abortion Clinic (this form).
2. Any supporting attachments.
3. For each physician performing procedures, either:
 - (A) A copy (in writing) of the physician's admitting privileges; or
 - (B) A copy of:
 - (1) his/her written agreement with another physician with admitting privileges; and
 - (2) a copy (in writing) of that physician's admitting privileges.
4. Payment made payable to "Indiana State Department of Health."

Mail to:

INDIANA STATE DEPARTMENT OF HEALTH
CASHIER'S OFFICE
P. O. BOX 7236
INDIANAPOLIS, INDIANA 46207-7236



Liam Lynn Morley

bread and roses



Studied Gender and Women's
Studies at Indiana University South Bend



Liam Lynn Morley

Apr 16 at 1:17pm • 🌐

...

Happy Easter! Reflecting on the morning that women held it down, believed, waited, and watched while men left, lost heart, and fainted. Paths to redemption have always been told through women's stories; don't let centuries of patriarchal readings of the Bible let us forget that!



12

1 Share



Like



Comment



Share



Liam Lynn Morley

Apr 14 at 11:20pm • 🌐

...

Reflecting today on Mary's pain as she watched her brown son die before her eyes by the violence of the state.



2

1 Share

It is finished, but our work is not.



Click here to see a list [Local doctors, women health advocates speak out about possible South Bend abortion](#)

by Heather Black, WSBT 22 Reporter



WSBT 22 FIRST. FAST. ACCURATE.



SOUTH BEND —

Around 25 local doctors and women health advocates are voicing their concerns about an abortion clinic wanting to come to South Bend.

They addressed the St. Joseph County Council Tuesday.

The issue wasn't on the council's agenda, but they used the public comment period to speak about what they say is a concern for women in the county.

They're concerned about the medical process to have an abortion and what they call a "bad track record" for these types of facilities.

Whole Woman's Health wants to make South Bend its next site for an abortion clinic, but more than 20 doctors, nurses and health advocates spoke against the process of the abortion.

"We see complication rates across a wide variety of studies. Those complications include things like hemorrhages. Some of those require transfusions in the ve to seven-percent category. Infections that can lead to sepsis and even death," said Justin, resident physician at local hospital.

STATEMENT ON PROPOSED CLINIC

WHOLE WOMAN'S HEALTH

"We respect all peoples beliefs and are here to serve women in the community who deserve access to our high-quality care."

Amy Hagstrom Miller
Whole Woman's Health C.E.O.

abortion
a b o r t i o n

ABORTION CLINIC CONCERNS

clinic#photo-1)

VIEW PHOTO GALLERY



4 photos (/news/local/gallery/local-doctors-women-health-advocates-speak-out-about-possible-south-bend-abortion-clinic)

AA

f

t



(mailto:?subject=A%20link%20for%20you&body=You)

Local OBGYN David Parker says he's seen women who regret their decision.

"In my practice, I've seen patients who have taken the first pill the mifepristone pill and have experienced regret and they have come to me asking me to help them. I don't want my baby to die what can you do?" said Parker.

In a statement Tuesday, Amy Hagstrom Miller, the president and CEO of Whole Woman's Health, says the clinics are "committed to improving people's lives by providing access to the best medical care, which included the full range of reproductive health services for women."

Granger Family Physician Laura McGuire says she's concerned about the former South Bend abortion clinic, which was shut down after failing the procedures of the state. "We know that there is an organization here that has the same kind of profile as Dr. Klopfer wanting to come back in our town," said McGuire. Miller says her group respects "all peoples beliefs and are here to serve women in the community who deserve access to our high-quality care."

The group that spoke out Tuesday wants the council to at least create a medical standard for the abortion clinic if it comes. The entire statement from Whole Woman's Health is below:

"Whole Woman's Health of South Bend joins its sister clinics in Peoria, Illinois and Minneapolis, Minnesota to serve women in the Midwest with the highest quality care; treating the mind, the body and the heart with the dignity and respect Midwestern women deserve at a challenging time in their lives. Women and families everywhere deserve access to high-quality reproductive health care, including safe abortion care. Whole Woman's Health has a long-standing commitment to providing that care with dignity and respect, and in areas where women's access to that care has often been denied.

We understand that abortion is a complex issue for many people and it often involves a deep examination of people's feelings and beliefs. We know women don't only experience unplanned pregnancy as a medical issue; we know it often involves a deep examination of peoples values. We respect all peoples beliefs and are here to serve women in the community who deserve access to our high-quality care.

Access to quality abortion services has been continually decimated in Mike Pence's Indiana communities, such as South Bend, and at Whole Woman's Health we are committed to improving people's lives by providing access to the best medical care, which included the full range of reproductive health services for women."

New abortion clinic applies for license in South Bend

By Margaret Fosmoe South Bend Tribune Oct 14, 2017

https://www.southbendtribune.com/news/healthandsafety/new-abortion-clinic-applies-for-license-in-south-bend/ricle_a9b47a26-1e28-5b10-82d7-4af30e060ec3.html

EXHIBIT 14
Legal Opinion to ISDH



The Austin, Texas-based Whole Woman's Health Alliance has applied for a license to open a family planning clinic that provide non-surgical abortions at 3511 Lincoln Way West in South Bend. The area has not had an abortion-services provider since 2015. Tribune Photo/BOB BLAKE

SOUTH BEND — A new Austin, Texas-based family planning clinic that would provide non-surgical abortions has applied for a license with the Indiana State Department of Health to open a location [here](#).

The firm Whole Woman's Health Alliance would base its clinic at 3511 Lincoln Way W., a short distance west of Bendix Drive. The building formerly housed a chiropractic clinic.

The nonprofit has asked the state to waive certain abortion-licensing requirements because surgical abortions would not be provided.

The organization already operates women's health and abortion clinics in eight cities, according to its website: Austin, Ft. Worth, San Antonio and McAllen, Texas; Peoria, Ill.; Baltimore, Md.; Charlottesville, Va.; and Minneapolis. It provides medication abortion to women who are up to 10 weeks pregnant.

According to a copy of the clinic's application, which the South Bend Tribune obtained via a public records request, patients seeking abortions at Whole Woman's Health in South Bend would take the abortion-inducing medication Mifepristone in the presence of a physician. One to two days later, they would take another medication at home. After that, they would return to the clinic for a follow-up appointment to confirm their pregnancy was terminated.

Jennifer O'Malley, director of the office of public affairs with the state health department, said the clinic's application is being reviewed.

This area has been without a provider of abortion services since November 2015. That's when Dr. Ulrich "George" Klopfer dropped his appeal of the state revoking his medical license amid allegations of violations of state laws and regulations. Klopfer had also operated clinics in Fort Wayne and Gary that were shut down.

Currently, the closest abortion services providers are in Merrillville, Ind., Chicago; Indianapolis; and Kalamazoo, Mich.

On the application, Liam Morley is listed as the proposed clinic's administrator. She was an employee for several years at the clinic Klopfer ran and in August 2016 identified herself to a Tribune reporter as director of the Pro Choice South Bend group.

Morley said at the time that Pro Choice South Bend, which provides community outreach for women seeking abortions, was not directly involved in efforts to launch another clinic.

The Tribune on Friday placed numerous phone calls and e-mails and left messages seeking comment from Pro Choice South Bend, but no one from the group responded. Morley could not be reached for comment.

On the application, the proposed clinic's medical director is listed as Jeffrey D. Glazer, M.D., an obstetrician-gynecologist who is licensed to practice in Kentucky, Indiana and Ohio.

Under Indiana law, any physician providing abortion services (whether surgical or via medication) must have admitting privileges at a hospital in the county where abortions are provided or in a contiguous county, or must have entered into an agreement with a physician who has admitting privileges at one of those hospitals. The measure was approved by the General Assembly in 2016 and signed into law by then-Gov. Mike Pence.

The ISDH provided The Tribune with a copy of Glazer's agreement with a local physician who has hospital admitting privileges, but O'Malley said state law requires the department to redact identifying information from the document, including the physician's name.

Members of the St. Joseph County Right to Life and Indiana Right to Life groups are encouraging supporters to voice their opposition to the proposed clinic. The groups have created an online petition that notifies state and local government officials of opposition to the clinic proposal.

"If there is a chance for us to stop this clinic from opening, we will do everything in our power to do that," Antonio Marchi, program director for St. Joseph County Right to Life, said Friday. And if the clinic opens, Right to Life members will make sure women who visit the clinic can get all the help they need without going through with an abortion, he said.

The Tribune on Friday contacted Whole Woman's Health Alliance and requested an interview with Amy Hagstrom Miller, the organization's chief executive officer and founder.

She declined the interview request. In an emailed statement attributed to her, she wrote, in part: "It is our commitment to go into places that are underserved and where women have suffered because so many clinics have shuttered due to continued political interference. South Bend women and families deserve access to high quality abortion care services..."

Whole Woman's Health was involved in a landmark case decided by the U.S. Supreme Court in June 2016. The court strengthened constitutional protections for abortion rights, striking down parts of a Texas law signed by then-Gov. Rick Perry that could have drastically reduced the number of abortion clinics in the state, leaving them only in the largest metropolitan areas. The court ruled that Texas cannot place restrictions on the delivery of abortion services that create an undue burden for women seeking an abortion.

The court found that Texas' restrictions — requiring doctors to have admitting privileges at nearby hospitals and clinics to meet the standards of ambulatory surgical centers — violated a prohibition on placing an "undue burden" on a woman's ability to obtain an abortion, the New York Times reported.

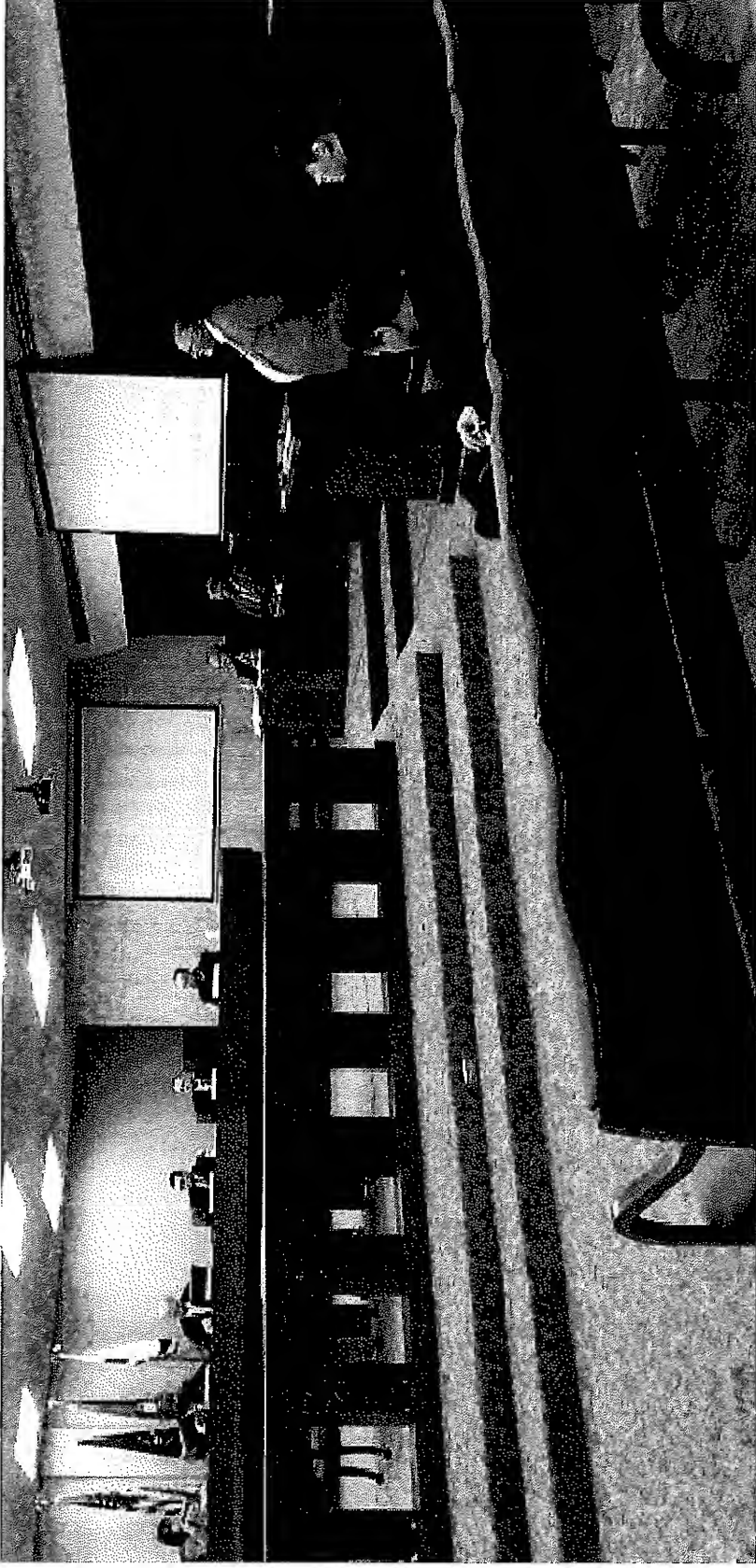
The Whole Woman's Health clinic in Austin, founded in 2003, was forced to close in 2014 as a result of the Texas law, but reopened in April 2017 after the Supreme Court ruling.

mfoismoe@sbtinfo.com
574-235-6329 / @mfoismoe

Group of doctors speak against South Bend abortion clinic Speakers urge county ordinance to address concerns

https://www.southbendtribune.com/news/local/group-of-doctors-speak-against-south-bend-abortion-clinic/article_8e28a70b-7a33-5593-80c5-0c55a16461f9.html

By Ted Booker South Bend Tribune Dec 7, 2017



Thomas Dickson, an attorney in Osceola, was among 30 people who raised concerns during a St. Joseph County Council meeting on Tuesday about an abortion clinic proposed in South Bend. Tribune Photo/TED BOOKER

SOUTH BEND — Several doctors were among about 30 people who told the St. Joseph County Council that if an abortion clinic proposed here opens, it could burden the medical community.

During the public comment period of Tuesday's council meeting, they argued that local hospitals would be compelled to provide treatment to women with complications from medication-induced abortions.

St. Joseph County Right to Life, which has launched a media campaign to oppose the clinic with billboards and various advertisements, organized the speakers for the meeting. Doctors, nurses and other anti-abortion advocates spoke for nearly two hours at the meeting, citing statistics to highlight the risks of medical abortions. No abortion access advocates spoke.

The anti-abortion speakers acknowledged the County Council has no control over whether Texas-based Whole Woman's Health Alliance, which runs clinics in eight cities, is approved to open at the building chosen for the clinic at 3511 Lincoln Way W. That decision will be made by the Indiana State Department of Health, which is still reviewing the organization's application.

Even so, the speakers urged council members to consider legislative actions they could take if the clinic opens as a way to address potential pitfalls with reporting patient complications.

Antonio Marchi, Right to Life's program director, says the clinic would likely underreport patient complications from medical abortions to the state department of health. That's because he suspects patients would often be treated for complications by local hospitals; in that case, complications wouldn't be reported to the state unless patients followed up to tell the clinic about them.

A spokeswoman for Whole Woman's Health didn't return a call or email seeking comment Wednesday, and someone who answered a message to Pro Choice South Bend's Facebook page said the group wouldn't comment because none of its representatives attended the meeting.

As it stands, abortion clinics are required to submit a terminated pregnancy report for each abortion to the state health department. That form requires them to indicate any complications, such as hemorrhaging.

Marchi said that if the clinic opens, the council should consider passing an ordinance to require the clinic and local hospitals to report all complications to the county, ensuring complete data.

Mike Trippel, the council's attorney, thinks the county elected officials, who oversee the county health department, would have the authority to approve such an ordinance.

Patients seeking abortions at Whole Woman's Health would first take the medication Mifepristone in the presence of a physician, according to the clinic's application to the state. One to two days later, they'd take another medication at home. After that, they'd return to the clinic for a follow-up appointment to confirm their pregnancy was terminated.

Medical professionals at Tuesday's council meeting argued that because the second pill would be taken at home, patients with complications would likely turn to local hospitals to treat complications. And in some cases, they say, hospitals would need to conduct surgical abortions.

Among the nine doctors who raised concerns was Kelly McGuire, with OB/GYN Associates of Northern Indiana who has hospital privileges at Memorial Hospital in South Bend and Saint Joseph Health System's Mishawaka Medical Center.

McGuire alluded to a patient who was treated for complications in November at the Mishawaka hospital after a failed medication-induced abortion with a provider in Chicago. She was eight weeks pregnant.

After a consultation, he said, the woman was scheduled to have a surgical abortion; but before that could happen, she came to the emergency room "bleeding heavily and in a lot of pain." He called the situation an example of what hospitals would see "on a regular basis" if the abortion clinic opens.

County Council President Rafael Morton, a Democrat, said Wednesday it is "too early in the process" to discuss whether a local law regarding abortion clinics could be considered.

The debate comes after the County Council voted 6-3 in March 2015 to reject a controversial bill that would have required abortion providers to have hospital admitting privileges.

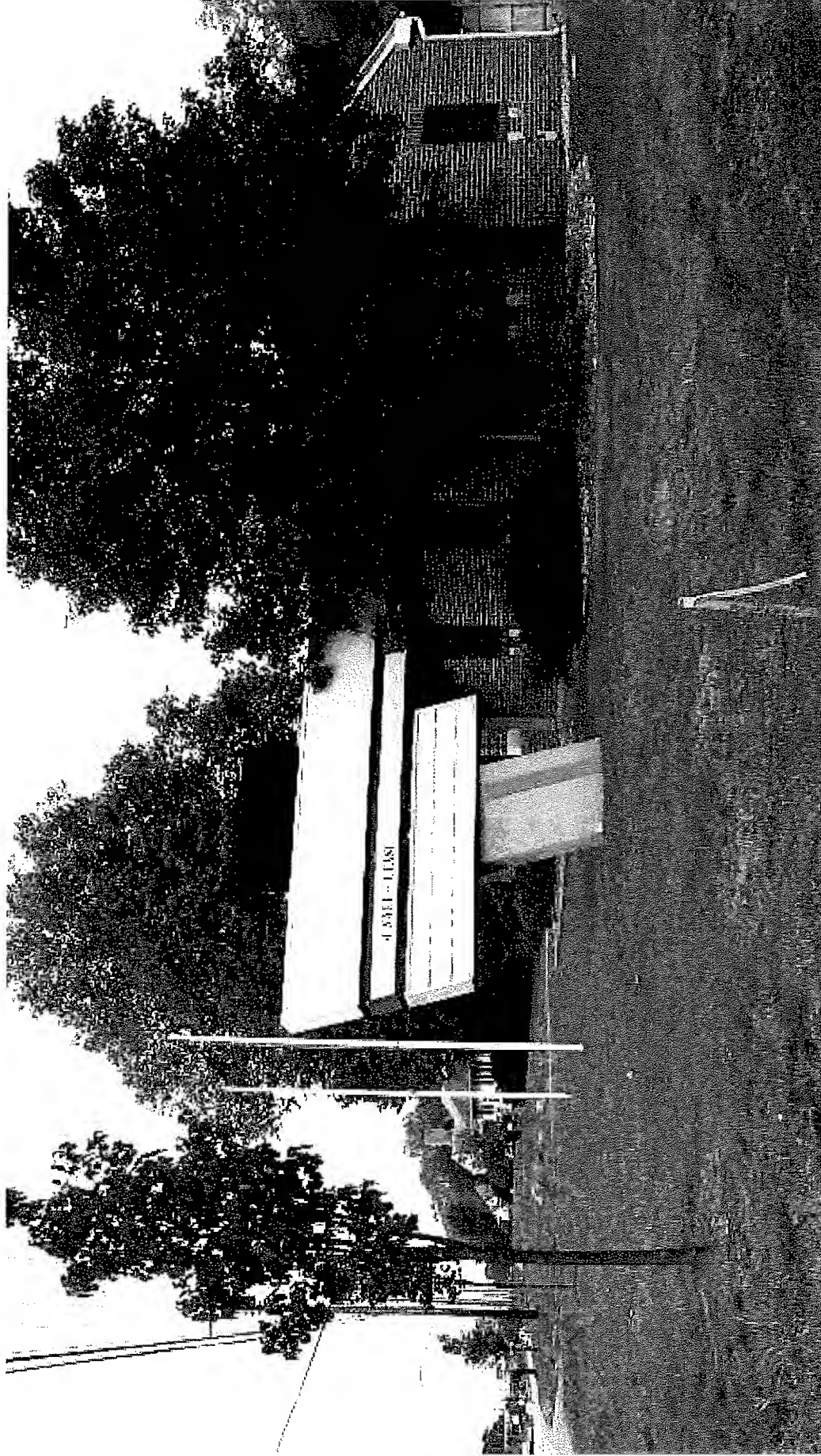
The area hasn't had an abortion provider since November 2015, when Dr. Ulrich "George" Klopfer — amid violations of state regulations — dropped his appeal of the state's revocation of his medical license.

In a statement Tuesday to WSBT-TV, Whole Woman's Health said in part that "access to quality abortion services has been continually decimated in Mike Pence's Indiana communities, such as South Bend, and ... we are committed to improving people's lives by providing access to the best medical care, which include the full range of reproductive health services for women."

@Tbooker24
tbooker@sbinfo.com

574-235-6070

Whole Woman's Health officially announces South Bend abortion clinic plans



Posted: Mon 4:20 PM, Oct 30, 2017 | Updated: Mon 4:36 PM, Oct 30, 2017

SOUTH BEND, Ind. (WNDU) Texas-based Whole Woman's Health has officially announced its plans to open a new abortion clinic in South Bend.

We first reported earlier this month that the group applied for a license to operate out of a building in the 3500 block of Lincolnway West.

Whole Woman's Health says it plans on opening the South Bend clinic as soon as possible.

Recently, U.S. Rep. Jackie Walorski asked the state health department to reject the group's application, saying that St. Joseph County has seen a "tremendous" reduction of abortions in recent years.

Whole Woman's Health says abortions are just one of the services they provide to women.

From Whole Woman's Health:

Today, Amy Hagstrom Miller, founder and owner of Whole Woman's Health, announces her latest endeavor to open two new abortion clinics in South Bend, Indiana and Charlottesville, Virginia under a non-profit Whole Woman's Health Alliance (WWHA). Hagstrom Miller operates independent abortion clinics in 16 states, including Texas where she won a major victory for women and families in the 2016 case, *Whole Woman's Health v. Hellerstedt*, the most consequential abortion rights case to go to the Supreme Court in a generation.

Both Indiana and Virginia are classified as "extremely hostile" to abortion rights, having passed new laws in recent years to burden women seeking abortion and force clinics to close. In 2014, some 95 percent of Indiana counties had no clinics that provided abortion care and 66 percent of Indiana women lived in those counties. Indiana now has only six clinics open to serve women in the state, dropping from 10 in 2011.

In 2014, Virginia had only 18 abortion clinics, representing a 14 percent decline in clinics from 2011. Now Virginia has just 13 open clinics. In 2014, some 92 percent of Virginia counties had no clinics that provide abortion, and 78 percent of Virginia women lived in those counties.

"As we witness ongoing attempts by the Trump administration to bully and block women who need abortion care, I'm proud to announce that we are expanding our healthcare work, to open two new non-profit clinics. Whole Woman's Health Charlottesville opened in October 2017, and we will open the clinic in South Bend as soon as we can. These two clinics play a key role in the Whole Woman's Health Alliance launch of a nationwide initiative to combat abortion stigma," said Amy Hagstrom Miller, founder and CEO of Whole Woman's Health and Whole Woman's Health Alliance. "Nearly a year after the election of the most anti-abortion administration in decades, Whole Woman's Health Alliance is doubling down on what we do best: providing compassionate holistic care and proclaiming loudly and proudly that every day, good women have abortions. We will go where they need us the most.

"We are so excited to welcome Whole Woman's Health into the Commonwealth, where they will continue to fearlessly care for women and families. And if I know anything about Amy Hagstrom Miller and her team – they won't let intimidation from anti-choice legislators or political battles slow them down," said Tarina Keene, Executive Director of NARAL Pro-Choice Virginia. "Whole Woman's Health has been a bastion of hope for women seeking honest, compassionate, effective abortion care for years. They inspired us to introduce a whole new wave of proactive legislation here in Virginia after Amy took on the state of Texas and TRAP laws in the landmark *Whole Woman's Health v. Hellerstedt* case, in which the Supreme Court ruled that medically-unnecessary regulations that impose an undue burden on a woman's access to abortion are unconstitutional. Charlottesville women and families are lucky to have such a great team bringing reproductive health care to their city, and we're thrilled to be one step closer to eliminating gaps in access to abortion in Virginia."

"At All-Options, we believe that everyone has the right to be supported in their decisions about pregnancy, parenting, abortion, and adoption. That includes having access to quality, safe abortion care without significant financial or geographic barriers," said Shelly Dodson, Center Director of All-Options in Indiana. "We are thrilled that Whole Woman's Health will be opening a clinic in South Bend, and look forward to having another provider to refer clients to in Indiana, reducing their need to travel out of state to find the abortion care they need."

"Virginians know that a woman seeking reproductive health care, including safe and legal abortion, deserves to be treated with dignity and respect. These are just the values Amy Hagstrom Miller and Whole Woman's Health bring to their provision of health care and we couldn't be more thrilled to welcome them to Charlottesville," said Anna Scholl, Executive Director for Progress Virginia. "Just a year after our hard-fought victory to roll back Virginia's sham restrictions on abortion providers, it's so gratifying to know that Virginia women now have an additional option for quality, compassionate, affordable reproductive health care access, and a fierce advocate for women's dignity and autonomy to boot."